Virtual Public Meeting on Patient-Focused Drug Development for Vitiligo

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Moderated by Robyn Bent
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A P Hollands E A R A N C E S

List of Attendees:

Robyn Bent, RN, Office of the Center Director

Kendall Marcus, MD, Division of Dermatology and Dentistry

Theresa Mullin, PhD, Office of the Center Director

Brenda Carr, MD, Division of Dermatology and Dentistry

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P R O C E E D I N G S

MS. BENT: Good morning. Thank you all for joining us today for our Patient-Focused Drug Development meeting for vitiligo. I'm Robyn Bent, the director of Patient-Focused Drug Development within the Center for Drug Evaluation and Research at FDA. I'll serve as the meeting facilitator for today's meeting.

We have a full agenda planned for the meeting today. We'll start with opening remarks from Dr. Kendall Marcus, director of the Division of Dermatology and Dental here in the Center for Drug Evaluation and Research at FDA. After Dr. Marcus's opening remarks, we'll hear from Dr. Theresa Mullin, associate director for Strategic Initiatives, who will talk about FDA's patient-focused drug development efforts. We'll then spend some time hearing from Dr. Brenda Carr, also from the Division of Dermatology and Dental, who will provide with a background on vitiligo just to set the stage for the meeting. And then we'll move on to our discussion with individuals are living with vitiligo and their loved ones and advocates.

We'll have two sessions. Our first session will focus on the health effects and daily impacts of vitiligo that matter most to individuals. Our second session will focus on your thoughts about current approaches to managing vitiligo. I'll better explain the meeting format and the processes right before we get to our first panel session.

Before we begin, though, I'd like to go over just a few logistics and housekeeping points. This meeting is taking place in the fully virtual setting and is focused on hearing from people who have personal experiences with vitiligo. Throughout the day, we'll have polling questions. You'll be able to access the polling questions using a cell phone or any type of computer or tablet. We'll talk a bit more about that in a few minutes. In addition to the polling questions, you'll have the opportunity to share your experiences by either using the chat feature in the bottom right corner of the meeting screen or by calling the phone number that we'll be putting on the screen throughout the meeting.

This meeting is being webcast, and the webcast is being recorded. Both the webcast and transcripts of today's meeting will be archived on our website.

With that, it is my pleasure to introduce Dr. Kendall Marcus, who will be providing opening remarks. I'd like to invite Dr. Marcus to now turn on her video and unmute to share her opening remarks. Thank you.

DR. MARCUS: Morning. Can you hear me?

MS. BENT: Yes, I can.

DR. MARCUS: Thank you. Good morning and welcome to this Patient-Focused Drug Development meeting on vitiligo. I'm Dr. Kendall Marcus, and I'm the director of the Division of Dermatology and Dentistry in the Office of New Drugs at the Food and Drug Administration. Our division reviews drugs for the prevention and treatment of dermatologic conditions including vitiligo. This is a very important meeting, and we're looking forward to hearing from patients, your loved ones, caregivers about how they think about vitiligo and what is important to them about potential treatments.

We're excited to have so many people joining us today with broad representation not only from patients and caregivers but also from advocates, from drug companies, and from academia. It's encouraging to see this high level of interest from a broad range of stakeholders in drug development for vitiligo.

I'm now going to spend a few minutes explaining the role of FDA and of drug companies in the development of new drugs in order that people here today understand where the FDA fits into the process. FDA protects and promotes public health by regulating drug development and research done by drug companies and other researchers. Drug companies are the ones who conduct studies of new drugs for medical conditions like vitiligo.

When they're finished conducting their studies, they submit marketing applications to the FDA to ask for permission to sell those drugs in the United States. It's our job to review the drug company's study plans and then to review their marketing applications to make sure that the possible benefits of a drug outweigh its possible risks. If we think the company has done a good job, shown that the drug works, and described the possible side effects, and that the benefit risk assessment is favorable, then we let them sell the drug in the US. This is how FDA regulates drug companies.

One final point that is important to understand is that FDA cannot direct or order drug companies to develop drugs for specific medical conditions. So where to patients fit into this process? We want to hear from you today to help us understand how patients view benefits and risks of possible new treatments for vitiligo. Today's meeting is about listening to you and your loved ones about how vitiligo impacts your life and what you value in a potential new treatment. I understand that not every person with vitiligo wants treatment. We're interested in hearing everyone's perspective, but we would also like to hear from patients who are interested in treatments because of the impact that vitiligo has had on their lives. Thank you.

MS. BENT: Thank you, Dr. Marcus. Thank you and your office for working so hard on this meeting, especially given how busy I know everyone has been. And now, I'd like to invite Dr. Theresa Mullin to unmute, turn on her camera, and provide us with a little background on the FDA Patient-Focused Drug Development program and patient-focused meetings. Dr. Mullin?

DR. MULLIN: Thank you, Robyn. Hi. I'm Theresa Mullin, the associate center director for Strategic Initiatives in the FDA Center for Drugs. I'll give you a little bit of background on this Patient-Focused Drug Development, for which is now a program, and what we try to accomplish with this effort. And so next slide please.

So what is Patient-Focused Drug Development? We define this to be a systematic approach to help ensure that the patients' experiences, their perspectives, their needs, and priorities are captured and meaningfully incorporated into drug development programs into our evaluation. And next slide please. And so Patient-Focused Drug Development meetings give us an opportunity for more systematic collection and listening to patients' perspectives and on the severity of their condition and of the impact of their condition on their daily life and their experiences with the available treatment options.

We've learned over the course of this effort that we've had underway for about eight years now that patients are uniquely positioned to inform our understanding of the clinical context for review and our regulatory decision making. And before the Patient-Focused Drug Development initiative, we had fairly limited ways to try to hear from patients. So the available mechanisms were generally in the context of specific application and a particular matter to do with that, and we would have limited participation of patient representatives, who because it was about a specific application had to undergo a fair amount of screening for conflict of interest. And so that really limited our ability to hear from the broader community. So these Patient-Focused Drug Development meetings give us a way to really reach out to a wider range of people who have a condition to hear their view and what they've been experiencing.

Next slide please. And so Patient-Focused Drug Development meetings are not only for FDA but also other stakeholders are given the opportunity to hear the patient's voice. And so I know that in the meeting today, we have a really great participation. We're really happy about the participation from patients and caregivers. We also know that there are industry parties on the call who may be interested in developing drugs to treat vitiligo as well as healthcare professionals, academic researchers, and others. And so it's a chance to just for a wide range of stakeholders, if you will, to hear patients' perspectives on this.

We began this back in 2012, and based on frankly patients coming and talking to people when they were in the middle of user fee negotiations about wanting more participation and more of an opportunity to inform FDA and others about what they were going through. And so in 2013 to 2017, we really launched this effort. And at that time, FDA conducted 24 of these meetings in different disease areas. By about 2016, though, patient groups were coming to us and saying, "Look. It's great that you're doing this, but our disease might not be among the number that you're able to do. Why don't you expand it?" So we expanded this to have an externally led patient-focused component to the program now.

And that's really allowed us to expand much more in our ability to hear what the patient's perspective is on their condition and the available treatments. And at this stage, we're actually developing guidance documents to try to help inform, collecting this information in a way that makes it maximally useful in drug development and for FDA decision making. And so that's another piece of what we have underway now.

Next slide please. So this slide just kind of shows you the snapshot of the different disease areas. I hope you can see it. The font is kind of tiny, but I think we'll have these slides. They'll probably be on our website later so you can see it. But it's basically a very wide range of disease areas that FDA has used, and in addition to those, as I mentioned, we've now had over 40 externally led meetings that FDA's had the opportunity for our clinicians to just go another step to attend and listen. These are meetings that are organized and conducted by patient organizations. And we've tried to support them in their efforts. So well over 60, almost 70 meetings to date in different disease areas. So it's been really fantastic.

Next slide please. So as Dr. Marcus was just explaining a little while ago, FDA's role is not one of conducting the trials or developing the drugs. But as part of our mission to protect and promote public health, we do include this monitoring and evaluation of the safety and effectiveness of new drugs and marketed drugs. We play a critical role in development, although we don't conduct the development activities. We don’t develop them or conduct the trials. But our review divisions like Dr. Marcus's division and others really conduct oversight throughout the development process and are able to advise companies to have a stronger development program, one that's more protective of patients and makes better use of the time that patients spend back in trials, and then that final stage of reviewing the submitted application and then following drugs once they're on the market to make sure they continue to be safe and effective. So that's the kind of role that FDA plays throughout this. And you can see where there are opportunities all along the way for patients to inform FDA and others about what matters to them in terms of benefits and risks.

Next slide please. So this slide gives you an overview. These patient-focused meetings have a town hall style to them. In this case, we’re going to have a virtual town hall. And it begins as we are now with this overview. And next, you'll hear from Dr. Carr about the clinical background and currently available treatments. And following that kind of stage setting, we move into that first session that Captain Bent described, which is an opportunity to hear more about the symptoms and daily impacts of the condition on the patients who are living with it and maybe their families as well.

And we've launched that with a panel. Hopefully, providing a diverse range of perspectives on patients or maybe caregivers who are living with the person who has the condition or living with the condition. And we see that as kind of a launchpad for the discussion that follows, pulling in the wider range of people who have the disease who are participating in the meeting.

And that session is followed by a session on current treatment options. Similar format. We begin with a panel discussion representing hopefully a range of experiences with different treatment opts that may be available. And that, we hope serves as a way to launch the broader discussion and hear from the broader community participating in our meeting about their experiences with available treatments.

Next slide please. I mean, each of these meetings is tailored to the questions for the particular condition that we're hearing about. And we encourage other participants in addition to patients and caregivers: advocates, researchers, drug developers, healthcare providers, and even government officials. But our focus is on hearing directly from patients and their caregivers. And so we're going to ask everybody else to remain silent and in listening mode, so that we can really have this be a platform for hearing directly from patients and caregivers and maximize our opportunity today for that.

And then, after the meeting, we have a docket that we keep open, an electronic docket, where people can submit additional information that they may think of later. It will be open for a while after the meeting. Some number of days after the meeting. And with the information that we hear today and receive today and that comes in through docket, we create a voice of the patient report to try to capture and faithfully reflect what we've heard from you all today.

And finally, the last slide -- next slide please -- provides you just the resources that you can avail yourselves to at any time. The report that we will produce will be on this webpage. You can get to this webpage by Googling, or whatever other search engine you might want to use, Patient-Focused Drug Development. And it'll take to you to this landing page where you can see the guidance we have in development, other programs, and all about these patient-focused meeting, including the externally led and other resources. And with that, we really look forward to hearing from you today and thank you. And I'll end. Thank you.

MS. BENT: Thank you so much, Dr.

Mullin. I think it's clear from the number of people participating in the meeting today that Patient-Focused Drug Development and these PFDD meetings really play an important part in incorporating the patient voice into medical product development process.

And so now I would like to ask Dr. Brenda Carr to unmute and turn on her video to begin her presentation that will provide us with an overview of vitiligo. Dr. Carr?

DR. CARR: Morning. I'm Brenda Carr. I'm a medical officer in the Division of Dermatology and Dentistry. And I'll be providing an overview of vitiligo. Next slide please. Here's an outline of my talk. I'll begin with the introduction, a few words on epidemiology, then clinical features, treatment, and the impact of vitiligo. Next slide please.

Vitiligo is a chronic acquired disorder of pigment loss. Characteristic lesions are white patches with sharp margins. Vitiligo results from destruction of melanocytes, and the pathogenesis is not entirely understood. There are number proposed theories as to the cause of the melanocyte destruction, the prevailing theory of -- autoimmunity. Next slide please.

The prevalence of vitiligo is estimated to be at 1 percent of the worldwide population. Nearly 50 percent of patients have onset before the age of 20 years, and onset in children younger than 12 years of age is common. Vitiligo affects males and females equally. Next slide please.

There are two major types of vitiligo. The non-segmental type is the most common form and presents bilaterally, symmetrically, generally, and is unpredictable in its course, which may be characterized by progression and appearance of flares. There are several subtypes of non-segmental vitiligo, including localized acrofacial, generalized, and universal. Segmental vitiligo generally presents unilaterally and is stable in its course. Initially, it may progress rapidly but ultimately stabilizes. Hair in affected areas may be depigmented, and vitiligo may involve the mucosa. Next slide please.

This picture depicts a patient with acrofacial vitiligo, which generally involves the head, hands, and feet. This particular variant is sometimes referred to as lip tip vitiligo because it involves the lips and the tips of the digits. Next side please.

This patient has generalized vitiligo, and you can see the widespread dissemination of disease on both of the sides of trunk and the upper extremities. Next slide please. This is another patient with generalized vitiligo, and this patient has prominent involvement of the face as well as the trunk and extremities. Next slide please.

This is a patient with universal vitiligo. And you can see the trunk is nearly completely depigmented with small islands of pigmented skin present. Next slide please.

And finally, we have a patient with segmental vitiligo, which is involving one side of the face. And you can see that some of the hairs in the affected areas are depigmented. Next slide please.

There are no FDA-approved products with vitiligo repigmentation as an indication. The only FDA-approved therapy with the vitiligo indication is monobenzone cream, which is no longer marketed, and it's indicated for final depigmentation in extensive vitiligo, so for removal of remaining pigment in widespread disease. Next slide please.

Topical therapies include corticosteroids as the first line treatment and used in several strengths and in different regimens. Calcineurin inhibitors may be the choice for areas that are vulnerable to atrophy, such as the face. And they may be used along with corticosteroids on alternate days with those steroids. Vitamin D analogs are less often used because the efficacy may be limited. Next slide please.

Phototherapy is administered using either light in the ultraviolet B wavelength or the ultraviolet A wavelengths. There are two categories of UVB therapy. Narrowband UVB treatment is phototherapy treatment of choice because of its efficacy and its good safety profile. Targeted UVB therapy may be administered using monochromatic excimer light via lasers or lamps. Psoralen with UVA light, photochemotherapy or PUVA, was the first form of phototherapy. And the Psoralen may be applied topically to individual lesions or orally if the disease if more widely disseminated. Current practices favor the use of narrowband UVB because of the safety profile of PUVA, which includes phototoxicity, GI distress, and increased risk of skin cancer. Next slide please.

Systemically, corticosteroids may be used to stabilize rapidly progressive disease. And they're most commonly used via the oral route but may be administered via other routes. There's limited information on the use of other immunosuppressants, such as methotrexate, cyclosporine, Cyclophosphamide. Next slide please.

Broadly, surgical therapies involve the transplantation of melanocytes from pigmented regions to the vitiliginous lesions with the hope being that the melanocytes will proliferate and populate the vitiliginous areas. Tissue grafts are accomplished by several methods. The punch technique involves obtaining the graft via biopsy techniques. In the suction blister method, the graft is obtained from a blister that's been created in the donor region. Cellular grafts may be used for wider spread lesions. These techniques are more complicated and expensive and involve the use of suspensions that contain keratinocytes and melanocytes. Next slide please.

Camouflage techniques include the use of coverup makeup, which is applied daily; tattooing, which carries a risk of infection, mismatch, or poor matching of the tattoo pigment with the native skin color. And the vitiliginous lesions may progress beyond the borders of the tattoos. Self-tanning products are waterproof creams that may provide coverage for several days. Next slide please. A possible adjunctive role for vitamins, minerals, and botanicals has been explored. Next slide please.

Vitiligo may significantly impact patients' psychosocial wellness. Some patients have reported feelings of disempowerment and loss of self-esteem, a profound diminution in the quality of life. Others have reported feelings of worry, anger, shame, and depression with impairment of social life. It is important to note that these sentiments don't characterize all patients with vitiligo as some patients are very accepting of the condition. Economic impact may include costs associated with medical office visits and cost of supplies, such as makeup. Next slide please.

So we're aware of unmet medical needs experienced by patients who have vitiligo. We're conducting this public meeting to hear comments about the impact of vitiligo on patients, caregivers, and family members. I want to thank you for taking the time to join us to share your experiences and your unique perspectives. Thank you.

MS. BENT: Thank you, Dr. Carr. I think that this is really helpful for us to have this presentation to set the stage for what we're about to hear from our panelists and meeting attendees who have lived experiences with vitiligo.

Moving on, I'd like to share with you a bit more about how this meeting will proceed. I'd like to start by saying. It's really been truly an honor to work with the panelists that you'll meet in just a moment as we prepared for today's meeting. And thank you to Drs. Marcus, Mullin, and Carr for the really helpful presentations that give us some context to think about as the next part of this meeting. That is really yours. So if you're new to the area of what FDA does and what patient-focused medical product development is, then I hope we just gave you a little bit of a background on that and especially on some of the key terms and words that will we'll using today.

Before we kick off this next part of the meeting where those of you with lived experiences with vitiligo are the center of this show, I just want to share a little bit of information, kind of an orientation, to help you understand the meeting structure and why we set it up this way because it's very intentional. Those of you who are viewing, representing yourselves, or loved ones with lived experiences with vitiligo, you are the experts. And the expertise that you have is what we're all here today to hear.

We've kind of flipped the script on the type of meetings that most of us go to where you have a lot of medical professionals giving presentations and having discussions while you listen. Today, we've reversed that. We've heard some opening remarks from some experts in their field, but you're the ones who are the expert in your field. You're the ones who know what vitiligo is like to live with. So our goal today, as we start this discussion portion of our meeting, is to really foster an open dialogue on personal experiences and perspectives on vitiligo.

Our two main topics for discussion are health effects and daily impacts of vitiligo, followed by current approaches to treatment. We'll kick off each session with a panel of individuals with vitiligo. There are five panelists for the first topic. After the panelists, we'll introduce our three discussion starters, and we'll broaden the dialogue to include other individuals and family members who are joining us on the webcast. Anyone who's watching the meeting who identifies as a person with vitiligo or a family member or loved one is welcome to participate. Aside from the panelists and our discussion starters, we don’t have anyone else identified to speak. So we need you to share your experiences for this meeting to be successful.

The purpose is to build on the experiences shared by the panel. I'll ask a number of follow-up questions. Throughout the day, polling will be done via computer or cell phone. And as I mentioned previously, we're taking comments from online through the meeting chat feature and via telephone. So if you've got something to add, this is your opportunity to build on the information shared by the panel in discussion starters.

And I really hope that you feel the

importance of your participation in the meeting today. To have your experiences and priorities heard not only by the FDA but by representatives from medical product developers, researchers, and clinicians about vitiligo and what you'd like to see happen to help those with vitiligo. So please take this opportunity, and we hope this will be your invitation to participate with us in the discussion.

We encourage you to call via phone to share your comments. When speaking, you may remain anonymous. I mean, you don't have to give us your names. You may state your names if you want. But what we really care about is your experience.

And we you call in, there's a couple of things that will help us. One is if you stay on the topic that we're discussing. Whatever topic we're talking about. If we're talking about symptoms, if we're talking about daily impact, to try and think about what topic is and stay as close to that topic as possible. It's also helpful if you can keep your points to maybe just one or two things, so that we can go to as many people who want to speak as possible.

In addition, for transparency, we request that at the time of your first comment that you disclose if you're affiliated with an organization that has an interest related to vitiligo or if you have a significant financial interest in vitiligo drug development. If you're submitting comments via the webcast, you can provide whatever name you'd like. Don’t worry about us being overwhelmed by comments. We can handle them. We'll try to summarize them as much as possible. We'll do our best to share the comments we receive via the web platform. If we're not able to read all the comments out loud today, your comments will be incorporated into our final meeting summary report called The Voice of the Patient report.

And as Dr. Mullin mentioned earlier, we also have a public docket for this meeting that will be open until May 10. We encourage you to share your experiences and expand on what we discuss here today through the public docket. The comments will be incorporated into our summary report as well. Anyone is welcome to comment through the docket, whether you're joining us via the web or you know someone who wasn't able to participate today but you think they have something to contribute. Please encourage them to submit their comments.

You'll find the link on the slide here, and we'll also e-mail this link to everyone after the meeting who registered via the event website. You can submit your comments as anonymous. And I want you to keep in mind that if you submit your comments to the public docket, the word public is there for a reason. This will go to the website. So please, again, think about how much personal information you want to share because we don't need your personal information. We care about what your experience is. So please keep that in mind. You can just say anonymous or leave that part empty when they ask what your name is.

So one thing that is very exciting about our meeting today is that we have had more than a thousand people register to participate in the meeting. Of the people registered, actually, I think it's probably about 700 of you are either people with vitiligo or loved ones, patient representatives. So now this is wonderful, and we're incredibly grateful for the support of the vitiligo community for this meeting.

But we also realize that there may not be enough time for everybody who wants to share their experience today to share their experience. So we're going to open a crowdsourcing website. Now this is a pilot program, and we're hoping that this will offer an opportunity or an additional way for people to share their experiences and interact with FDA. Our plan is to open the site later this week and to keep it open for approximately two weeks. As with the comments that are submitted to the public docket, you're able to participate anonymously.

We're still putting the finishing touches on the site. So for those of you who are registered for the meeting, please keep an eye out for an e-mail announcing the availability of the site. And for those of you who are viewing without registering, we will share the meeting information or the crowdsourcing information to our meeting website. Information shared through the crowdsourcing site will also be incorporated into the meeting summary report, The Voice of the Patient report.

Moving on, there are a few ground rules for our discussion today. We are here, first and foremost, to listen to those with vitiligo and their loved ones. We'll try to accommodate everyone who wants to speak. We're happy to see a number of those who represent research and medical product development registered for this meeting. We believe that the input we hear today will be important for you as well. We just hope that you are able to stay in listening mode.

And FDA staff really is here to listen as well. We know that you may have questions about drug development or drug review. If you have specific questions, we encourage to share them via e-mail with our FDA staff. Our contact information is on the meeting website. We'll get back to you with more information following the meeting.

As has been described, our discussion today is focused first on the health effects of vitiligo and daily impacts and then the approaches to managing those health effects. Our discussions may touch upon scientific treatments. However, the discussion of any specific treatments should be done in a way that helps us to understand the broader issues, such as what health effects are being addressed and how that is meaningful to individuals with vitiligo.

Our discussion is going to focus, again, on health effects and treatments. We know that this is a very complicated issue. There are many concerns and many questions you have and thing that you have to think about living with vitiligo and getting the support that you need. Those are all important. Today, we hope to focus on the topics that FDA needs the most input on, so that we can best fulfill our role in medical product development and decision making. And we certainly understand and respect that not everyone who has been diagnosed with vitiligo chooses to treat their vitiligo. But our conversation today, because we're the FDA, is going to focus a little bit on treatment and what matters to patients as far as treatment.

So while you take in the information on this slide that outlines how to actively participate in the meeting, I'm going to take this opportunity to ask my FDA colleagues on the FDA panel to turn on their video and introduce themselves because I want you to see that we do have a lot of people. Unfortunately, the virtual setting keeps you from seeing them sitting on a panel the way they would usually in our face-to-face meetings. But this gives you the opportunity to see that we do have a number of people here. So let me start with Dr. Marcus.

DR. MARCUS: Hi, everybody. Welcome.

MS. BENT: Thank you. Dr. Targum?

DR. TARGUM: Hey, everybody. Good morning. Welcome.

MS. BENT: Dr. Trajkovic?

DR. TRAJKOVIC: Good morning. My name is Snezana Trajkovic. I'm a clinical team leader at the Division of Dermatology and Dentistry in the Center of Drug Research.

MS. BENT: Thank you. Dr. Carr?

DR. CARR: Good morning and, again, welcome.

MS. BENT: Thank you. Dr. Reyes?

DR. REYES: Hi. Good morning, everyone. I work in Drug Safety Surveillance at the Center of Drugs. I'm excited to hear about everyone's experiences today.

MS. BENT: Thank you. Dr. Marquart?

DR. MARQUART: Good morning, everyone. I'm Laura Marquart. I'm a dermatologist, and I work in the Center for Devices in Radiologic Health. So we look at the devices that would be used for vitiligo. Thank you.

MS. BENT: Thank you. Dr. Chung?

DR. CHUNG: Everyone, I'm Yujin Chung, reviewer from the Division of Clinical Outcome

Assessment. We're under Center for Drug Evaluation Research.

MS. BENT: Thank you. And Dr. Imperato?

DR. IMPERATO: Morning, everyone. I'm a physician in the Center for Biologics Evaluation and Research. I'm very much looking forward to hearing the lived experiences with vitiligo.

MS. BENT: Great. Thank you. And last but not least, Dr. Mullin?

DR. MULLIN: Hello. Good to join you again. Theresa Mullin associate director for Strategic Initiatives in the Center for Drugs. Thank you.

MS. BENT: Thank you. You're all welcome to turn off your video now if you would like. So thank you. From time to time during the meeting, we'll turn back to our FDA panelists to see if they have any questions or if they have any follow-up or clarifying questions for anything that we just heard. I'd also like to take this moment to introduce my colleague Shannon Cole, who will be keeping an eye out for comments that come through the internet. She'll be sharing those comments throughout the meeting.

Good morning, Shannon.

MS. COLE: Good morning.

MS. BENT: Shannon will also be coordinating with our other colleague Lena Murduke, who you'll be speaking to if you call in to provide comments via phone. And we'll have some polling questions today. And we're using a third-party application called Mentimeter to run our polling. Polling on Mentimeter's site menti.com is anonymous and can be done via cell phone or on your laptop or tablet. Please note that we're not tracking individual people's answers. We'll only see the responses grouped by option. You can access the Mentimeter poll in two ways. You can use your cell phone camera to view the QR Code on this slide, which will take you to the survey, or you can go to www.menti, M-E-N-T-I, .com. And use the digital code on this slide to enter the survey.

So with that, let's begin a polling question. So please get your cell phones or computers ready. Okay. So for Question One, we're starting with some basic demographic questions so that you can get familiar with the polling platform. And the first question is pretty straight forward. It is where do you live. I'm sorry. I'm not seeing the demographic question on the screen. Thank you. Okay.

Where do you live? You have two options because we're very DC centric right now. Option number one is within the Washington, DC metropolitan area, including Virginia and Maryland suburbs. Option number two is outside of the Washington, DC metropolitan area.

And so while you're completing the polling questions, I'm going to share with you one of the challenges of the virtual setting. So there is a little bit of a lag time between when we speak here on the backend of the meeting and when it's broadcast to the meeting participants. And so that lag time can be 20 to 30 seconds. So you'll see that as the answers for the polling kind of trickle in.

For some of the questions, you will have one answer, or you may be able to select one answer. For others, you may be able to select multiple answers. These polling questions are really meant to be a discussion aid for today. They are not meant to be in any way a scientific survey.

So okay. Great. So it looks like right now, everything is working. I don't think that we're having any challenges with the application. And I think that, as you can see, and this is truly exciting to us and one of the benefits of the virtual meeting setting, is that we have just a small percentage of people who are answering from the DC metropolitan area. And we certainly have been able to reach a much larger group of people through the virtual setting. As you can see, there's 88 or 87 percent of people are outside of the DC area. And that is always great for us to see.

So now let's move onto the next question. And that is have you ever been diagnosed as having vitiligo. And so there you have two answers: yes or no. I'll just give it a few more seconds. The answers kind of come in.

All right. Great. So from this point on, we're going to ask that polling questions be answered only by individuals with vitiligo or someone who is answering on behalf of a loved one with vitiligo. And so moving onto the next question. That would be what is your age. Remember, if you're answering for a loved one, please answer with their age. And the options that you have are younger than eight years old, eight to seventeen years old, eighteen to twenty-nine years old, thirty to thirty-nine years old, forty to forty-nine years old, fifty to fifty-nine years old, and sixty years and older.

Great. This is great. It looks like we have a really good representation across kind of all the age ranges. And so that's wonderful. I think one of our goals in this meeting really is to hear from as broad a group of people, a diverse a group of people as we can hear from. And so this is very exciting to see the distribution. So thank you all for that.

Let's move on briefly to the next question, which is do you identify as male, female, or other. Wonderful. Okay. So we're seeing that we have a few more women participating in the meeting than men. But it does seem like we have a pretty good representation of both men and women. It doesn't look like we have people who identify as other who are participating in the polling but, hopefully, are participating in the meeting.

Let's move onto our next question, which is where is your vitiligo located. And for this one, you can select all that apply. And so the options that we have are scalp, face and/or neck, hands and/or feet, trunk, arms and/or legs, skin folds, such as the underarm area, genitals, such as the groin, or other areas not mentioned.

All right. Great. And so it does seem like we're seeing people who have experiences with vitiligo in all areas of the body. So that will be helpful for us as we speak to kind of lived experiences with vitiligo to get different perspectives from people who have vitiligo impacting different areas. And so my thanks to everyone.

Before we move onto our panel discussion, we have just one more question. And that one kind of goes back to one of the presentations that one of the things that Brenda talked about during her presentation or Dr. Carr talked about during her presentation. What pattern does your vitiligo appear in? Focal, where it's depigmentation is limited to a few spots in one area of the body. Segmental, loss of skin color occurs on only one side of your body. Generalized, pigment loss is widespread across many parts of your body. Other or I'm not sure.

Okay. So it looks like we have a large representation of people who have generalized vitiligo. We also have a number of people with segmental, a few with focal or other, and people who maybe don't know or don't want to talk about exactly which one it is or perhaps more than one. So okay.

Thank you all. We certainly have a range of people participating today, and that's great. It's really exactly what we hoped for.

So with that, let's start with our first panel now. So as we mentioned, topic one will focus on the health effects and daily impacts of vitiligo. And we have five panelists who will start off the session by sharing their experiences. In about 30 minutes when our panelists are done sharing their experiences, we'll move to the interactive portion of the meeting by asking about your experiences. And if there's something that you hear from our panelists that really resonates with you or you want to share a bit of your own experience, please consider sharing your comments via the web or closer to the end of the 30-minute period. Maybe around 11:15 Eastern time. Maybe a little bit later. You want to give us call at 1-800-527-1401 to share your experiences. You should also know that if you call in and are placed on hold, the hold music will not be music. It will be this meeting. So you won't miss out on hearing from our panelists if you call in to speak.

Now we're going to turn the meeting over to our panelists. And I'd like to start by inviting Sharon to share her experiences with vitiligo. So Sharon, if you would like to turn on your camera and unmute, we would be grateful, and we look forward to hearing from you. Thank you.

MS. KING: Thank you so much, Robyn. Good morning, everyone. My name is Sharon King. I'm the founder of the Litty Ligo Outreach and Advocacy Network. I'm here to share my experience.

So imagine yourself in the sixth grade. Now imagine yourself going to a new school in a new town with a condition that you can't explain to your peers. I was emotionally overwhelmed. I was a little devastated when I first got diagnosed when I was 12. You know I'm very dark skinned. My father's from Panama. My mother is from New Jersey. And I used to live in a predominantly white town, and I got tormented for my skin, my features, my hair, my lips, everything. So when I -- you know? -- got diagnosed in 1999, my 12-year-old mind, I really thought that vitiligo was my own fault for wishing to be white. You know? It's really jarring when you are -- you know? -- around people that you want to call your friends, and they literally just make you feel unwanted, not just -- you know? -- for any other reason than what your skin looks like.

So when we went to the dermatologist, we didn't really have a lot of options. The options were cream, the lightbox. But the lightbox wasn’t something that interested me because the side effects scared me frankly. So I opted out. And the dermatologist didn't really have any other information outside of that.

So as time passed, I just kind of coped with my vitiligo. You know? My surroundings were much more important to me. You know? Like I said, I moved from a predominantly white town to an underserved, very diverse neighborhood. Nothing like I'd ever experienced. So there was a lot of things going on. There was violence. There was death. There was a lot of things that were regular that I had to worry about. So for me, I minimized my feelings for my vitiligo.

Depigmenting. Like I've literally gone from having vitiligo on 70 percent of my face to not having any at all like you guys can see now. And that was hard. It's happened about three or four times. But the last couple of times, I was luckily in a place of acceptance. So you know? It was different. But you know? It does still scare me that at any time my skin can decide that -- you know? -- my pigment can go. And it does scare me.

When I was younger, personal relationships were very, very hard. You know? I'm already this 12-year-old girl trying to -- you know? -- navigate my own feelings with my skin. Then -- you know? -- I have to deal with the questions, the stares, people asking me all these things that I don't know the answer to and that I'm not ready to answer frankly. You know? I was literally crippled by anxiety. Like I didn't want to laughed at just for literally sitting there. You know? I wasn't warned about that. The reactions and stuff. And my teachers were just as unprepared. I actually had a teacher that had focal vitiligo, but he never acknowledged it. So I was like, "Well, maybe I shouldn't either." And so I didn't. And whenever those things came up, whenever -- you know? -- questions about my skin or things came up, I found myself in verbal altercations, physical altercations because it was maddening. It's so frustrating where -- you know? -- there's this person. I'm like, "He won't talk to me but okay." So it was hard. You know?

Luckily -- -- you know? -- my mom kept me active. When we moved to this new neighborhood, she was -- you know? -- very aware that -- you know? -- I got to stay active to stay out of these streets. So you know? I settled on basketball. Love basketball to this day. And I found -- you know? -- my tribe. I found my people, my support system. And I found my voice.

And speaking of my support system, I found a really good friend. And I tell him I'm going to tell this story whenever I have the chance. So Christopher J. Brookins [ph] was the most -- well, not the most -- but one of the most popular boys in school. He was tall -- you know? -- played basketball, and all the ladies loved him. And then one day we were in class. It was sixth grade. We were in class, and -- you know? -- some kids were making fun of me. And I'm -- you know? -- kind of a shell of myself at this point, and he stands up. He goes, "You know? Sharon's going to grow up, and she's going to realize she's beautiful. And she's not going to pay any you guys any mind."

And even though, I didn't feel that way at the time, it was a turning point for me. I decided like, "You know what? I may not feel this way, but I'm going to fake it until I do." So you know? I've always had this kind of confident presentation, which it was true but it wasn't. I wasn't truly confident until honestly about four or five years ago. So that's a 20-year battle.

At home, I was very supported. My father, my sister, my grandmother, all live with vitiligo. So you know? People understood in my household. So I didn't have to deal with the things I dealt with outside of that. My son. When my son was eight years old, we had a conversation because -- you know? -- I saw his face one day coming out of school. You know? I asked him like, "Do your friends ask you about my skin?" And he said, "Yeah." You know? Eventually, he was kind of reluctant, and eventually, he was like, "You know? They ask me if you got burned, and it makes me upset." And you know? I had to explain it to him and explain what vitiligo was. And eventually, with that education, he became an advocate. He was able to put together the words and to really articulate how it makes him feel when people make fun of his mom's skin.

I really, really hope that this gave you a little bit of insight into how it is to live with vitiligo. So even though, I personally don't want treatment. There are so many people out here that do, that want it, that need it. And everyone deserves to heal in their own way. So thank you so much for having me.

MS. BENT: Thanks so much, Sharon. And thanks for being the first one to speak. But most importantly, thanks for sharing your experiences.

We're now going to move onto Tonja who's going to share her experience. You've already turned on your camera. Perfect. And unmute. Thank you so much. And please go ahead.

MS. JOHNSON: Good morning. My name is Tonja Johnson. I was diagnosed with vitiligo in 2013 at the age of 43. The impact of losing so much color so quickly really bothered me for a while and caused me to go into deep depression and seriously contemplate suicide. I literally wanted to die. So I wouldn't have to deal with this awful disease that had taken over my beautiful black skin.

Losing over 85 percent of my color has had me wondering who I am and asking myself, "Where's the beautiful dark-skinned woman I used to know?" I often feel like I'm losing the very thing that identifies me as a black woman. So am I really losing my identity as a black woman or the skin that identifies as a black woman? Unfortunately, many may say it's just skin, but for me, it goes much deeper than just skin color. I'm learning the fact that although I'm losing the skin color that identifies me as black but not the characteristics that I value as a black woman.

Working in public helped throughout a global pandemic, and seeing firsthand experiences of other people dealing with COVID as well as myself being diagnosed with COVID was very stressful and caused my spots to become wider and new spots to appear on my legs. There are still so many unknowns to COVID-19 that I still wonder about the future impacts that it will have for those of us living with vitiligo.

Although I've lost a significant amount of color, I have gained much more. Vitiligo's impact on my growth and self-confidence becoming stronger, I have learned how to ground myself, become resilient, and focus on loving my new skin color. There's a newfound love for who I am today and a level of confidence that I did not have before my diagnosis.

I embrace my vitiligo and founded Beautifully Unblemished vitiligo support group here in the State of Florida. I am passionately empowering individuals to focus on body image, building their self-esteem, and loving the skin that they're in. I share my journey today because I now stand in the strength of family, friends, and even strangers who offer their love, support, and encouragement. I live a happy, beautiful, and exciting life with vitiligo, and I wear it with great poise and grace. Thank you.

MS. BENT: Thank you so much, Tonja. I suspect that many of the experiences that mentioned are going to resonate with a lot of the meeting participants, and we'll touch more on some of these topics during our panel discussion.

So now I'd like to turn it over to Mark

who is going to share his experiences. Mark, please go ahead.

MR. BRAXTON: Greetings and thank you for the opportunity to share my story. I have some things written down, but I can also speak from my mind. But I don't want to do that because I'll go on forever.

But my journey with vitiligo started in my 20s, and now I'm almost 50. A couple of years shy from 50. And I struggled with it until 2019 when I decided to no longer let vitiligo take me on its journey. It had to live life with me. So my mindset has changed on how I view my vitiligo.

But here's pretty much my story and how it affected me. It started as a small spot on my hand, and it was really tiny. But then, it started to spread all over my body over the years: my hands, arms, arm pits, torso, back, chest, legs, feet, thighs, around my mouth, and genital area. Vitiligo forced me into self-isolation, extreme introversion, and at times fully closed me off to the world. That was a choice I made because of having my vitiligo.

It stopped me wearing shorts, going to the pool, beach, social gatherings, festivals, even my college homecoming, which I really enjoyed. But I was ashamed to be in front of my colleagues and my close friends and my fraternity brothers. I didn’t want them to see me like this because this is not how they knew me. And besides removing my pigmentation in various areas, vitiligo made me extremely insecure about my body. I battled with low self-esteem, depression, low self-image. And I had to cope with the daily anxiety attacks when moving out into society or into social settings outside of work.

It also created challenges when engaging in intimate settings because I wasn't secure with my body, and I was afraid for others to see what I looked like. And you know? One thing I would always hear and I'd never like, people would say it doesn't bother me. And I understand that. It doesn’t bother you because you're not the one living with the condition. And you have to take into consideration the person that was living with vitiligo and how it affects them internally.

But the current pandemic that we're living in right now brought on additional stress. I notice small spots appearing on my legs and some on my hands. And then they started to merge together. So now those small spots are large spots on my body.

And I want -- I guess -- everyone to understand that vitiligo is not just a condition that removes the pigmentation on the surface of the skin. It affects you physically, emotionally, spiritually, and psychologically. It creates challenges in social circles, families, friendships, personal relationships, and in the professional setting. Vitiligo is more than what you see on the outside. Vitiligo is what you can't see that's happening in the inside, and that's what causes the most damage for someone like me in living with my vitiligo.

And thank you for the opportunity to share my brief story.

MS. BENT: Thank you so much, Mark.

We're now going to hear from Andre. Andre, please go ahead. Welcome.

MR. JOACHIM: Okay. Hello, everyone. My name is Andre Joachim. I am 47 years old. I've been living with vitiligo about 29 years now. I worked as a youth and family therapist before I came into my professional. I'll take you back on a journey with me before I was diagnosed and when it first started happening.

Just imagine you're walking down the street. And then you look, and people are staring at you. People are gawking at you. People are -- you know? -- mouthing words like, "Oh my God. What's wrong with you?" Calling you a monster. Children are running from you. That was a typical day in my life.

I remember going to my child's soccer game and his football games, and kids would stare. And he would be afraid to even walk with me, hold hands with me because of so many stares. I know when I first got diagnosed there was not a lot of awareness on vitiligo. Fast forward to now. A lot of people know about vitiligo because of certain celebrities and everything. But it still makes it very hard because there's a lot of the public who's very unaware of things that go on with vitiligo.

I remember before I came into my profession and trying to get a job. I say very low-level skill jobs where -- you know? -- you might be working at McDonald's, Burger King, Taco Bell. Very entry level jobs. Well, when I went into get interviews and everything, I would do great interviews, but everyone wanted to focus on my vitiligo. When I'd tell them it's an autoimmune disease, they would be stuck on that word disease.

So like sometimes my friend would be like, "You're a shoe in for the job. You should get it. They need people desperately." And then after the interview, one of my friends told me like, "The reason why you didn't get hired was because they were scared that you would run off customers. They were scared that customers would not come back because they think you have this disease that will be given to them or passed onto them." You know? That was very disheartening and heartbreaking to me.

And so instead of focusing on that, I went to school where I said, "You know what? I'm going to find a job where people won't focus on so much on my skin issues or how I look." So I became a therapist and everything. I've been working with youth and family, but also I decided to devote my time to the vitiligo community.

And you know? I see that we all go through these different stages of like grief and loss. Losing our identity in the process of losing our skin color. And you know? We go through sadness. We go through depression. We go through anger. We go through denial. We go through bargaining. And some of us get to a place of acceptance. I'm at a place of acceptance.

And I do like rocking the skin I'm in, but I'm a human. And I go through the same emotions that everyone goes through. So there are days that I wake up, and I have trouble just looking in the mirror. There are people that I know that I've talked to in the community that also have had trouble. And I went through my share of suicide ideation, and I see other people experience that now. And as therapist and as a person in general in the public, you understand that suicide ideation and suicide is a very huge topic in America today or across the world.

So I think focusing on issues to help individuals with vitiligo is very important. And you know? While it may not present so much as an issue to people who accept it, there's a large majority who have issues. You know? Some things I can't do that I want to do is go out into the sun. I want to be able to go on the beach and do all these I did. You know? Travel without any problems and without the sun burning me severely and everything. But that's an issue that I have to deal with. And I think that's definitely something that a lot of people can relate to having vitiligo. You know?

And so as far as my thoughts and everything, I'd say as a community, as everyone, we should be doing something, anything, we can to help -- you know? -- come up with treatment alternatives and solutions to help individuals who have vitiligo because it can be emotionally damaging. It can be physically limiting.

So in the grand scheme of things, I think that -- you know? -- all of us have had these experiences as Sharon, Tonja, as Mr. Braxton had pointed out. So you know? With that, I thank you for hearing me out and hearing me speak. And thank you very much.

MS. BENT: Thank you so much, Andre. That was a really, really very thoughtful presentation. We really appreciate you taking your time to kind of share it with us.

As our final panelist for this session, we're going to hear from Jackie who is going to share her experiences. So let me invite Jackie to turn on her camera, unmute. And please, Jackie, go right ahead.

MS. GARDNER: Thank you. Good morning

to everybody. So I guess what's left for me to discuss on the impact is the input from a 30-year veteran. I was diagnosed with vitiligo in 1989 during my third pregnancy. And it has ebbed and waned over the years, but it sounds like not unlike a lot of other panelists. It's really snowballed over the past 12 to 18 months. Even after 30 years, I don't leave the house or answer the door or even go to the mailbox in daylight without covering the vitiligo on my face.

Corrective cosmetics have been both my saving grace and the bane of my existence. The daily process is very tedious and time consuming. It can take anywhere from 30 to 45 minutes in the morning. There are multiple layers of products that take various times to dry and set. And the base coat is always a DHA sunless tanner product that takes anywhere from eight to twelve hours to develop, which of course takes advanced planning. And the flipside is removing it all at the end of the day. DHA is only good for a couple of days before it starts turning very orange. So it has to be exfoliated and reapplied at night in order to be redeveloped by morning.

This particular coping mechanism has created challenges, not only for me but for my family, such as having overnight guests in our home. I'm not comfortable coming out of the room in the morning unless I've applied my full makeup, and I won't remove it until the last person is in bed at night. This has also precluded overnight traveling with friends in situations that might require sharing a bathroom. I'm just not comfortable with that situation.

And I've also developed some very difficult side effects, such as intense burning and itching. Mostly on the areas that are depigmenting but not always. I mean, my skin just itches. But I awaken at night with burning and itching. And I'm scratching, and I'm rubbing. And the more I scratch or rub or even touch sometimes, the worse it gets. It just feels like cactus needles stuck in my skin. And many times, the only thing that will help is just to get up and get ice packs. After that, it'll usually resolve within an hour or so.

And I've also developed a very intense heat intolerance. Making it difficult to participate in any outdoor activities in temperatures over 70 degrees. Some of these and other side effects that I've experienced are the result of the comorbidities that I've developed. I have Hashimoto's thyroiditis, metabolic syndrome, adrenal insufficiency, chronic fatigue syndrome, Raynaud's phenomenon, and I'm pre-diabetic.

Of all of these, I would say that chronic fatigue's had the greatest impact on my life. I could literally sleep 24 hours a day and never feel rested. I have to just almost throw myself out of bed in the morning. My endocrinologist once told me she didn't know how I was standing in front of her with the flatline cortisol levels that she was looking at in my labs. So for me, getting up at six o'clock in the morning is somewhat like trying to fight through general anesthesia.

And that's what I have. Thank you for the opportunity to share my perspective.

MS. BENT: Thank you so much, Jackie. And wow. There is a lot to unpack from all of these experiences. And we really need to thank Sharon, Tonja, Mark, Andre, and Jackie for sharing their experiences. And they did it to really help move the field of vitiligo forward. So thank you for that.

So how many of you have heard your or your loved one's own experiences reflected in the comments shared by at least one of the speakers today?

So in a virtual setting, it isn't really possible for me to see you nodding or applauding the way we usually see in our PFDD meetings. So we're going to use some polling questions to get some feedback from all of you who are joining us online.

But before we move to the polling, I'd like to add just another plug for sharing your experiences with us. If you have thoughts to share related to the discussion questions on the screen, please submit them via the web or over the phone. For those of you who'd like to call in or submit comments to be shared, as a reminder, here is how to do it.

Okay. So moving onto polling. And we'll leave this screen up for just another minute so that if those of you who want to access the QR code or be reminded of how to access through the website, we'll give you just another minute to look at the polling question information on the bottom of this slide. All right. So just as reminder, polling is still limited to participants who either have lived experiences with vitiligo either as someone with vitiligo or as a family member or a loved one.

Okay. So while we're waiting for those of you watching to call in to share some of your experiences, I'm going to turn to my FDA colleagues to see if they have any follow-up questions at this point for our panelists.

Okay. Let me turn briefly to Shannon. Shannon, have we received any comments through the online portal before we move onto polling and then to our discussion starters?

MS. COLE: Yes. Thanks, Robyn. We

have received several comments through the webcast chat. And several participants are kind of echoing these sentiments of the panelists and saying that what the panelists have shared really resonates with them. But others are also mentioning that they too experience comorbidities with their vitiligo, such as diabetes and Hashimoto's thyroiditis.

Another commenter noted that it's much more than just the emotional and mental health effects of vitiligo. They suffer from always burning in the sun without the protection of the darkened skin, and they have to slater in sunscreen or stay in the shade. And sometimes even sunscreen doesn't help to stop getting sunburnt. This individual also noted that having to explain to every new romantic partner that their skin looks different under their clothes is definitely a challenge for them as well.

We also have another commentor who has shared their experience with their child who has been very cheerful and fun-loving and loves going to school. But when their child was diagnosed with vitiligo about a year ago, it has definitely kind of changed their personality and outlook on life. And they wanted to bring awareness to body shaming in schools and the vulnerabilities that children have with that.

MS. BENT: Great. Great. Thank you. That's really, really helpful. To those of you who are sharing your comments and your experiences, please keep doing that. We are looking at them, and they will be included in our meeting summary.

So at this point, we're going to turn back to polling questions for a brief moment. And our first polling question is what aspects of your vitiligo are most bothersome to you. And for this one you can choose up to three areas. And the options that we have -- I'll just wait for a moment. There we go. The options that we have are patterns of depigmentation, amount, or extent of depigmentation; location of depigmentation; loss of hair color, such as hair on the scalp, eyelashes, eyebrows, or beard; sun sensitivity, which I think Shannon just touched on, such as sun or temperature or sweat; and other effects not mentioned.

All right. So it looks like the amount or extent of depigmentation and the location of depigmentation are particularly bothersome to people. But it also looks like the skin sensitivity, such as sun, temperature, or sweat is also a large concern. And that seems to be consistent kind of with what we've heard from our panelists. So thank you all for providing feedback to that.

Moving on maybe to our next question. And this is similar but a little bit different. What do you find to be the most bothersome impacts of vitiligo on your daily life? And so these you can also choose up to three answers. These are a little bit more about the impact on the daily life as opposed to specifically the vitiligo itself. And the options are time or cost of daily maintenance; refraining from activities, such as school, work, sports, and social activities; self-consciousness or embarrassment; bullying or discrimination; impacts on relationships with family and friends; impact on sexual intimacy; or emotional or psychological impacts, such as anxiety, fear, or depression; or other impacts not mentioned. And of course, we understand that there is, obviously, some crossover. None of these happen just alone.

And I realize that for most of you, if it's as small for you as it is on mine, it's a little bit challenging. It looks like the self-consciousness or embarrassment is at about 27 percent and emotional or psychological impacts is kind of that mustard yellow on the right at 25 percent. And then refraining from activities, such as school, work, sports, and social activities is the 18 percent mustard yellow on the left. And so it does look like -- you know? -- we are seeing a lot of impacts from vitiligo.

And so while we're waiting for additional responses to these polling questions, I'm going to take this opportunity to introduce our discussion starters. And at this point, I'd like to invite our discussion starters, Alicia, Paul, and Olle

-- I'm so sorry -- to turn on their cameras for brief introductions. Alicia, if you'd just like to take a moment to introduce yourself just very briefly?

MS. ROUFS: Hi. I'm Alicia Roufs from Minnesota, and I am a lifer with vitiligo at 43 years.

MS. BENT: Thank you. Olle?

MR. WINST: Yes. Hello. My name is Olle.

MS. BENT: Olle. Sorry.

MR. WINST: I'm 18 years old, and I'm from Sweden actually. And I have had vitiligo for as long as I can remember.

MS. BENT: Thank you. And Paul? Paul, you're muted. There you go.

MR. MONTERO: Hello. I'm Paul Montero. I'm from Holland from the Netherlands, and I am the chair of the Dutch Vitiligo Organization. I'm also a board member of the Vipoc, the Vitiligo International Patient Organization Committee. And I have vitiligo as a youngster of 12 years, but when I became older in 2008 until 2012, I became totally white. So I transformed from Indonesian roots to a total white man. I have vitiligo universalis.

MS. BENT: Thank you so much. So looking back, I really appreciate you joining us. And I'd also like to invite our panelists from session one to be ready to kind of turn on your cameras to participate as discussions permit. But I will say that it sounds like we have a good number of callers on the line. So we will be turning to those callers as well.

So to start out, it looks like there are a number of ways, looking back at the polling questions, that vitiligo impacts people's lives. And so maybe I can start here with Alicia maybe if you want to tell us a little bit more about how vitiligo has impacted your life, Alicia?

MS. ROUFS: Thank you. As I said, I'm a lifer with vitiligo. So I've gone through the childhood all the to adulthood with vitiligo. And as a child, it was very difficult especially being from a small town with no one else with vitiligo having anyone to turn to is very isolating and hard. Bullying was definitely a factor. I was called spot. That was kind of my nickname for people unfortunately, and it definitely was a hard thing to grow up with.

Being an adult with it, I'm probably about 85 percent depigmented. And so now dealing with vitiligo as an adult is more of the limitations of being able to be outside, going to the beach without wearing head-to-toe UV clothing or sunscreen, baseball games for my son is difficult. So it's the hard part of dealing with it. You know? Growing up with the psychological issues, developing who I was because of that, and now being an adult and dealing with just the day-to-day life of vitiligo and also having other autoimmune diseases too besides vitiligo. So that’s kind of my background with having to deal with vitiligo in my life.

MS. BENT: Great. Well, not great. But thank you so much for sharing your experience. That's very helpful for us to hear. Before I turn to our other discussion starters or panelists, I think we have someone on the line. Do we have Cindy on the line? Can we put Cindy on? Cindy?

CALLER CINDY: Yes.

MS. BENT: Hi. This is Robyn. You're on the line to talk about your experiences with vitiligo. If you want to share one or two things for a minute or two, we'd really appreciate it.

CALLER CINDY: Yes, ma'am. I developed vitiligo when I was 20 years old. Up until that point, I had done local modeling and that kind of stuff. And my disease started on my face. So you can imagine the psychological side of that that I went from being somebody that was photographed and out in front of people to having the changes of skin color. And it provided a lot of depression and psychological issues to the point where I wouldn't want to participate or go out and limited my involvement in things.

And then I met a man, and I got married. And he had no issues with that, and we have children. The main part of that is I'm a third-generation person with vitiligo. And while my home was very supportive, I want something to happen in some sort of development that my children won't have to go through the name calling and the mean things that people say and the hurtful things, such as the staring and all of that. And while I tried to be supportive and strong for my kids to make it fun -- when my daughter was little, I used to let her play connect the dots on my legs just to have some fun with it. And she used to love that. She thought it was cool.

But I'd like to see something that this is a generation that we turn it around and change that, help to educate society on it, and give a little more empowerment to those of us who are dealing with the loss of pigment that we can feel more comfortable and not feel like outcasts and be stuck in our homes and that kind of thing.

MS. BENT: Thank you. Thank you. I think that's a point we've heard raised by several people today. And it's certainly very important.

Thank you so much.

I think we have one more caller on the line right now. Rochelle [ph]? Maybe you can put Rochelle through, and then we'll turn back to our panelists to see if they have anything to add. Rochelle, are you on the line?

Okay. I don't hear Rochelle. So let me then turn back to our panelists. Actually, let me ask Dr. Marcus. I think she has a clarifying question that she would like to ask. So go ahead, Dr. Marcus.

DR. MARCUS: Thank you. Thanks, Robyn. And thanks to everybody who's shared so far. It's really been helpful to hear about all of the challenges that people go through. There are physical challenges, psychological challenges, and even career challenges as we've heard from some people.

We've also heard from people that the challenges bring about a good deal of strength and resilience although everybody has a very unique path it sounds like in terms of when and how they get to that point of acceptance of strength and resilience.

And I've also heard that it's very difficult, particularly for children in experiencing bullying and isolation.

And so my question is, when would people consider taking a treatment that may be very effective but may also have some potentially significant side effects associated with it? From listening to everybody today from my perspective as a regulator -- you know? -- I'm trying to understand when people would consider taking a treatment because of the impacts that it's having on their lives versus trying to push through and come to a place of acceptance.

MS. BENT: Great. And so let me see. I don't know if there's anyone who'd specifically like to speak to that. Olle, did you want to speak to that? Would you be interested in speaking to that, maybe we should turn to Paul? Do you have a preference?

MR. MONTERO: Yes.

MS. BENT: Okay.

MR. MONTERO: Sorry?

MS. BENT: Go ahead, Paul.

MR. MONTERO: Before, I was an entrepreneur in healthcare and successful entrepreneur in healthcare. And in fact, I was born about the fact that people weren't always doing in discussion with my clients in the hospital. They're looking at my hands not looking what I'm was trying to explain to them. So my communication was just focused on my hands and not on what I was telling in fact. And that was bothering me. And at that one moment, I started to try some therapy, UVB, et cetera, et cetera.

But the most important thing I think when I lost my color was that I transformed -- I told you -- in a period of four years into a white person. But I've lost also my genetic properties. I was proud of my color. I was proud of my Indonesian color. And I changed from a skin type five into a skin type one. So I told you I was so proud of my Indonesian roots, of my Indonesian skin. And I was successful.

And I'm proud that a man with

Indonesian roots could be a successful business man, in fact, in Holland. You know? Indonesia is a colony of Holland. So that's the reason I was proud that I became a successful business man. And because of the vitiligo I was worried that I wasn't -- yeah -- I know -- I was proud to be a successful business man --

MS. BENT: Right. It sounds like kind of that loss of identity, loss of kind of --

MR. MONTERO: Yes.

MS. BENT: -- cultural identity has been something that has really impacted a lot our panelists. I think, Mark, you had your hand raised. Did you want to speak to Dr. Marcus's question?

MR. BRAXTON: I do. And I don't want to speak on behalf of everyone with vitiligo. But I run a podcast, and I talk to many individuals with vitiligo. And when it comes to treatment, it works for some, and it doesn't work for others. And I think that's the challenge that we have when we look at getting a treatment. How successful will it be to cure my vitiligo?

I did the cream. The cream did nothing for me. So I stopped. I know some people that have tried the UV treatment; it did not work for them. And they stopped. So I think when we're looking at treatment, we want something that's going to work for -- I guess -- a majority of the population and not just for some and with minimum side effects. I think that's what scares a lot of people. The side effects could be worse than the actual treatment. So I feel like that's one of the concerns I hear in hearing some of the stories from people that have tried various things. Thank you.

MS. BENT: Thank you. So Olle, did you want to add anything here?

MR. WINST: About treatment --

MS. BENT: And just about your experiences. I know that you're one of our younger panelists for this round.

MR. WINST: Yes. Yeah. Just a quick summary. Well, I can weigh being pretty lucky from a young age, because as I said, I have had vitiligo since I can remember. But in the early stages, I only had one spot on my knee, one on my foot, and just behind the eyelashes. And so it covered itself really. But then out of nowhere when I was 15, it just exploded, yeah, over all my hands, down on my face, all over my arms. So I feel that kind of shock still until this day. Now it's been three or four years since all of that came. I'm still pretty shocked because it happened so quickly. So quickly. And I think that's just crazy how it's changed us so quickly.

And with that said, I was pretty lucky in the young years because I never got really bullied for it because people didn't really see it. Nowadays, of course, I cover myself up every time I go out. But when I was younger, I don't have really much to say from them stages when I was younger because I was pretty lucky then.

MS. BENT: Great. Thank you for sharing that. And I think that's one thing that I heard while kind of talking to our panelists, and I think something that we'll hear maybe a little bit more as we continue our conversation is this kind of the challenge of never knowing what to expect and not knowing if your vitiligo is going to change over time and the impact maybe that that has.

Let me take a moment now. We do have a number of people on the line. So let me see if we've been able to get Rochelle on the line. Do we have Rochelle on the line? Hello?

MS. BRINKMAN: Sorry. I don't like a lot of jelly.

MS. BENT: Hello. Can you hear us? Hello?

MS. BRINKMAN: Hello?

MS. BENT: Yes. Hi. Is this Rochelle? Hello?

MS. BRINKMAN: Hello? This Lavis Brinkman [ph].

MS. BENT: Okay. Were you interested in sharing your experiences with vitiligo?

MS. BRINKMAN: Oh, sure. I'm sorry. I

wasn't prepared. Sure. I don't have vitiligo. My son has it. He was diagnosed at age 12. And it came from being bullied at school. That summer it appeared on his. I didn't even know what it was. My daughter was getting ready to be a flower girl at my niece's wedding. We were tying on his shoes, and I looked down on his knees. And there's these spots. My brother-in-law's a physician. And so when we went to Philadelphia, I asked him, "What are these spots on Derek's [ph] legs?" And he said that it's vitiligo, and I need to get him checked out. And sure enough, it was.

It started in his legs, and now he is 18. His first year of college. It's on his face. His legs are mostly white. His feet are mostly white. For him, he's adjusted very well. The first thing that I did was to get him around other children that had it. So I was part of a group called ADRS, which was very helpful for him because he was able to talk and share. They were able to communicate and share their stories. And then I got him around adults that had it. Very positive. Like Andre who's on the panel. Just being around adults and how they adjusted well has helped him at this point. It was very scary to see him go to college to be honest because when we changed schools from the one where he was bullied at to another one, his vitiligo had just started. And so it grew with him. So he didn't experience bullying. Going off to college in a different state in a different environment for people who did not know him was very scary for me. He just went with the punches. He has adjusted very well. I have not heard anything about being bullied. He's distant with just everyone else. And so I think is that one of the great things for him.

I do know that when he gets in the sun, his skin turns very red. But he's a boy. I cannot convince this boy to put on suntan lotion to save his life. But he doesn't complain. I just know that his skin gets really, really red in the sun. But as far as his attitude at this point, he's adjusted very well. And I think it just has a lot to do with the positive people that I've placed in front of him. And so I'm really glad of that experience.

MS. BENT: Great. Thank you so much. I'm glad that he's having a positive experience. It sounds like that was due in part to family support.

Let me turn now to Heather. I think we have Heather on the line?

CALLER HEATHER: I'm here.

MS. BENT: Hi, Heather. Please go ahead and share your thoughts on vitiligo. If you could, maybe touch on the impacts vitiligo has on your daily life, maybe on the best days and the worst days. But if there's something specifically you'd like to speak to, we would be happy to hear that as well.

CALLER HEATHER: Okay. A brief history. My mother had full body -- she's Caucasian, but she went completely like albino white. Then she started to take an arthritic medication, which is involved in some of those trials. And she started to repigment, and it was quite a challenge for her to live all that time -- you know? -- turning white, et cetera.

But I was born with one white patch that eventually turned into what they call the lip and chip: the elbows, the hands, the face, the eyes, the knees, the vaginal area -- you know? -- the feet. And I tried different medicines. Nothing light related but topical creams. One of them that burned actually my face pretty badly. It didn't work very well.

But I'm in the entertainment industry. So I'm in front of the camera. And I've used a mineral based makeup to conceal. Some of the other people were speaking about. It's quite a process, and it does not stay on now that we've got COVID masks, et cetera. It's always rubbing off. And so when I have to deal with a makeup artist, I have to, "Don't touch it. It's going to come off. We're going to have a problem." You know? And it's a quite a challenge.

Sunshine. Very athletic. I'm also a dancer. I mean -- you know? -- so I can't go outside that much anymore. Just sort of have a restricted life. I've tried to get on some of the clinical trials because I do believe certainly from that experience with my mother that there is something out there that may actually have benefit for people that are suffering to realize some of their color return.

But yes. All the points hit. You know? The social sort of embarrassment. You know? A little bit of fear about doing things with other people. Swimming. You know? Just a lot of that stuff.

Did I answer what you asked me to answer? Did I sort of go off?

MS. BENT: Yes and no. That is fine. I think you gave us a little of our context and really a better understanding of kind of how it impacts your daily life. I mean, talking about the makeup and things like that. So yes. Thank you very much.

So let me turn now back to my panelists and discussion starters and see if there's anything that you would like to add to what we've heard so far, as far as the impacts of vitiligo. Particularly, maybe, how vitiligo impacts your life on the best days or on the worst days. And so maybe, Andre, did you want to speak to this a little bit?

MR. JOACHIM: Yes.

MS. BENT: Okay. There we go. Perfect.

MR. JOACHIM: Yeah. I definitely want to speak to this. I think it's important that we recognize that -- you know? -- a lot of other autoimmune conditions have had like spotlight on them. They say that people with lupus, they experience extreme -- I'd say -- emotional state. And I also, like, just from my interaction with the vitiligo community, I see a lot of these things as well.

I think definitely there should be focus on research that really pinpoints how the emotional is connected to individuals with vitiligo. Because from a lot of my conversations and even from myself from my own experience, I see that some of the things that go on in my day-to-day life has an even stronger emotional toll and tie to it depending on what it is. And you know? As a therapist, I have to sit back and have a self-talk and be like, "Well, is this really worth getting this upset over?" and different things like that. I know not everyone has those tools to be able to really look at these things.

But I definitely think that there's a huge emotional tie, psychological and emotional effects, that really affect people with vitiligo. And I think that's definitely something that maybe research should definitely focus on as well not just on just say medication or treatment or other alternatives and everything. Really getting a full depth and understanding of what individuals face on a daily basis while dealing with the emotional connections that -- you know? -- may throw off our lives or -- you know? -- affect us in certain ways.

MS. BENT: Okay. Thank you. I think that is also a very important point.

So now let me turn to the phones for a moment. I'm trying to kind of go back and forth. I think we have Catherine on the line. Catherine?

CALLER CATHERINE: Yes. Hello. Can

you hear me?

MS. BENT: Yes, we can. Thank you.

CALLER CATHERINE: I just want to thank you for having me and thank you to the rest of the panelists. It's been really, really eye-opening. I'm a Caucasian woman that developed vitiligo in my mid-20s. I'm now 40. And the impact has been really the majority of my body in a very sadder, taxing way. I'm also a professional woman outward thinking professional job where I cannot hide.

And I don't want to reiterate what others have said about the impact on lifestyle and trying to stay out of the sun and how that impacts -- you know? -- my day-to-day routine. But I want to really talk about my desire to kind of blend. I think that this has led to blend my skin color. And that's really like through a lot of personal experimentation with this disease as it has progressed. We've all talked about the creams and the lasers and vitamins and everything. But it really brings up, I think, with doctors and people that I've spoken with about it ever since the duration of wanting to blend, of wanting to deal with the different colors that exist on your body, and how that changes.

So it's been a lot about acceptance for me as others have already discussed. But I wanted to also just kind of mention and speak directly to the question that one of the regulators asked about treatment. You know? Based on my level of acceptance with my body and how it's changed and how that's affected my life, I still would certainly be willing to take a risk with possible therapies.

I understand that regulators do a benefit risk assessment. I'm actually in that industry. But patients do too. And this disease really provides, I think, at least for me, a higher risk tolerance, even though I've gone through waves of acceptance of my body and my skin. So I think that we all are changing all the time. And stress certainly impacts that, but I'm excited about what the FDA is looking at here and taking patients thoughts into account, so that we can look at other options, not only to treat the disease but also the underlying impacts to behavior as well. Thank you so much.

MS. BENT: Thank you for taking the time to call in. I'd like to take a moment now to turn to Dr. Chung. If you'd like to turn on your video? I know you have a question. Maybe we'll start with our panelists, and then maybe we can turn to someone on the phone as well.

DR. CHUNG: Thanks, Robyn. So I remember Jackie mentioning -- I don't think I heard a lot of other people talk about this before -- that when she's maybe sleeping at night, the affected and unaffected areas of her skin -- I remember -- saying there's severe burning and itching. It doesn't seem to be related to the sun exposure. And I'm just wondering if any other people have experienced that as well -- I'm curious -- because I only remember Jackie talking about it. So yeah.

MS. BENT: Okay. So Olle, do you want to speak to this? I see you have your hand up.

MR. WINST: Yeah, yeah. Sure. I can

only say that any without being out in the sun and having some pain on my vitiligo, I have had a few times not many times. But then, I have maybe like four or five times, but then it has been only on my spots on my hands but not anywhere else on my body. But I've actually had it but not very often. But when I've had it, it has been only on my hands.

MS. BENT: The pain and the itching and things like that?

MR. WINST: Yeah. Mainly itching. Not necessary pain but more itch.

MS. BENT: Okay. Thank you. So let me see. Mark, did you want to add to that at all?

MR. BRAXTON: I do briefly. I'm not sure if my camera's on. But I noticed that when my spots are spreading, they start to itch first. You know? And it doesn't matter whether it's the summer. It doesn't matter whether it's winter, spring, fall. You feel that itch, you look, and it starts a new spread. Or a new spot is starting to form. I've never had any pain but definitely the itching.

MS. BENT: Great. Thank you so much. Is there anyone else who'd like to add a comment about the itching or pain or anything like that before I turn to our meeting participants who are on the phone?

Okay. So let me then turn to our meeting participants on the phone. Maybe we can go to Greg.

CALLER GREG: Hello.

MS. BENT: Hi, Greg.

CALLER GREG: How are you doing?

MS. BENT: Hi. Great. Thanks. So we have you in the meeting. So if you could share any of your experiences in the next minute or two, we would very much appreciate that.

CALLER GREG: All right. Thanks. Well, thanks, everyone, for doing this. This has been great. You know? I can relate to so much that everyone has been talking about.

But you know? The one thing that I wanted to share that I don't think anyone's really mentioned has to do with the social and emotional kind of piece. I'm also 40 years old, and I was diagnosed with vitiligo when I was about seven. And you know? In my teens, I started to develop substance abuse issues. You know? And I definitely looking back on it now and all the work that I've done to overcome my substance abuse issues, I definitely contribute vitiligo to kind of affecting that and being a part of that. You know? Feeling insecure and a lot of anger and everything that a lot of people have expressed regarding vitiligo definitely caused me to abuse drugs and alcohol. And it was just one thing. You know? A number of things contributed to my substance abuse, but I definitely would say vitiligo. So I really wanted to share that now.

Also I'm 39 years old now. I've been sober and in recovery for 12 plus years. So I've overcome that, but also, like a lot of other people have shared, I'm fairly comfortable with my vitiligo today. And I think a lot has to do with it. But two things: one is the work that I've done in recovery has helped me with dealing with my vitiligo and also psychotherapy. I've been in psychotherapy for years. And that has definitely helped a great deal. So the gentleman who just spoke earlier about the emotional piece and talking about that. And I think I've been lucky to have a great therapist and people to support me in my vitiligo journey.

The other thing, just really quick, I have a 20-month-old daughter. My first child. You know? She started to develop some patchy white spots on her skin. And you know? She was dealing with eczema. And my wife, she's a physician, and she was kind of just like putting it off, like, "I think it's just a side effect of the eczema." You know? But I couldn't stop thinking about it. You know? Worrying that she had vitiligo. I get very emotional. You know? So I just really wanted to express that. I'm lucky. We just went to a dermatologist, and I got confirmation that it's not vitiligo. And I told the dermatologist that was worth the $25 co-pay. You know? And I would have paid $500 to hear that from a dermatologist. But that just goes to show you the effect of vitiligo. You know? I worry that my daughter might have it. And so once again, I appreciate you guys doing this, and I really hope positive things come from it. So thank you very much.

MS. BENT: Thank you so much for sharing that. And I think we touched earlier on kind of the unknown of vitiligo for yourself, but I can only imagine the challenges it has when it comes to the unknown for your kids and your other loved ones.

Before we move onto other people on the phone, let me take this moment to turn to Shannon to share some of the comments that we've received online. And as a reminder, I think it's become clear to us that we're not going to be able to hear from every single person that we want to hear from today just by sheer numbers. And we do appreciate you calling in, but please know that anything that you share with us will be included in the report even if we're not able to get to all the comments online. And we will be opening that crowdsourcing site.

But Shannon, please go ahead.

MS. COLE: Thanks, Robyn. Yes. As Robyn mentioned, we're receiving many webcast comments. And we can't get to all of them, but they will all be included in the Voice of the Patient report. But we're receiving several comments about itching and skin sensitivity from more than 10 people.

And one individual shared that their itching feels like tiny bee stings, and they never know when it will happen. And it goes on for about 30 minutes to an hour before it will ease. They've also shared that they have heat sensitivity, and they didn't realize that this could possibly be a side effect of vitiligo. They also shared that they have other autoimmune issues as well.

We're also hearing a lot on the webcast about the emotional impacts of vitiligo, such as suicidal ideation, anxiety, depression, embarrassment, feeling ashamed. And people are sharing that it's difficult to go out in the summertime. One individual shared that patients need more tools to address social stigma, personal anxiety, and loneliness, especially for them who grew up in rural towns where there's little understanding and underwhelming amounts of resources. And so they expressed the great need for these resources as well.

Another commenter shared that they work as a registered nurse, and their vitiligo has increased significantly with the stress of caring for their COVID patients. And they cannot figure out what is triggering this immune response. They've increased their sensitivity to light, and they must wear polarized sunglasses as well. And they've experienced their skin burning very quickly in the sun, which affects their ability to do yardwork, their ability to exercise, and participate in outdoor activities. And they've stated also increases their risk of secondary infections.

MS. BENT: Great. Thanks so much, Shannon. I know that we've had over a hundred comments so far coming in, and so you're doing an amazing job of kind of keeping track of those and sharing them with us. So I really very much appreciate that.

So now I'm going to go back briefly to our people on the phone. And not to be confused with the Alicia on our panel, I'm going to go Alicia on the phone.

MS. ARCHIBALD: Hi. This is Alisha Archibald. Can you hear me?

MS. BENT: Yes, I can.

MS. ARCHIBALD: Hi.

MS. BENT: Hi.

MS. ARCHIBALD: Hello. First of all, thank you to everyone on the panel. This has been great. I'm friends with all of your panelists except for the last one, Jackie.

My vitiligo started almost seven years ago. When mine started, I started with just a little small spot on the front of my head, and I was getting ready for work one morning. Let me preface this by saying, only one person in my family that we knew of had vitiligo, and that was my grandmother, my dad's mom. Okay. So when I saw my first spot, it was just a little spot on my forehead. And so I'm getting ready trying to get ready for work, and I thought maybe I burned my face with my curling iron. So I just kind of rubbed it with my finger -- you know? -- trying to flick it away. And I rubbed it again, and it was about the size of a dime. And instantly, I knew what it was. I just said, "Oh my God. I know what this is." And so it freaked me out. It scared me.

So I just watched it for a few days. And it was amazing to me because I had not noticed it. And it seemed like it just appeared overnight for it to be that size. So in my mind, I'm wondering, "Why didn't it start out smaller?" or, "Why I hadn't I noticed this?" And so, again, that was seven years ago.

Well, for like three years past that, I just kept watching it. I saw other small spots starting to develop on my face. That was where I saw it for about three years. And I started to get what they call the butterfly effect, what a lot of vitiligo patients have. Same thing with people with lupus. So there are a lot of questions. I didn't know a lot of people who had it. I had just gone through a really stressful time in my life the year before. I didn't think I was stressed at the time.

But when they took my call, they asked me what did I want to discuss, and I said, "Well, gosh, there's so many things." Everything that the panel has discussed I've experienced it. So it's been an array of emotions. But what I told them I wanted to discuss was just the mental effect. I've accepted vitiligo. But what I've found, even in my own vitiligo community, sometimes when you say you've accepted it, still some people are like, "Well, I love mine. I'm rocking mine." And I love mine too, and I've accepted it. And I appreciate Andre. I've met Andre. I've spoken Andre several times. But there are times like he said when I go past the mirror -- and I'm going to try not to cry -- but there are times when I go past the mirror, and -- you know? -- there are times when it does affect you psychologically.

And I just had that experience last week.

When I accepted it and decided I'm going to live with this, I'm not going to wear makeup trying to hide it anymore, that was back in 2019. I was getting ready for a party, and I was putting makeup on. I've never been a person to wear a lot of makeup. And I've always been pretty confident. Had self-confidence. But two weekends in a row, I was getting ready for a party, and I was putting all this makeup on around my eyes trying to cover it up. But I made that decision at the end of 2019 that I was going to accept it. If this is what God has for me, this is how it's going to be. And it was almost like when I accepted it, that's when I really started to lose my pigment.

Well, now at this point, pretty much the whole top half of my body has lost pigment. I'm losing pigment on my knees, my legs, my feet. So it is generalized. It's all over my entire body. I'm a professional person.

When it really started, when I started

to lose color, I was working at a bank as a banker. So I had people in front of me all day long every day. So I had a woman sit in front of me. And sometimes it's hard for them to focus on what we're talking about because they're looking at you and looking at your hand when you're pointing at the documents and saying, "Sign here."

So I had a lady walk out of my office, and then she returned back the next day. And she just propped her arm up at my office door and asked me, "I've been meaning to ask you. Did you have some kind of chemical peel? I mean, what happened to your face?" At that point, when she asked me that -- you know? -- I was pretty confident, and that comment didn't bother me then. But it's comments like that.

I had a little girl ask me in my office, "Why is your face so dirty?" So it's some many different things. It does affect you psychologically. So even though, I've accepted it. And then I started my group. I started a group here in Athens, Georgia, simply because my grandmother, she lived with it. But she suffered with it. And I just wanted to --

MS. BENT: Thank you so much, Alicia. I'm so sorry to cut you off, but unfortunately, we have a lot of people that we need to hear from today. But your experiences are really valuable, and it's very helpful for us to understand kind of everything that you've gone through. So I hope that you will consider kind of participating also in the crowdsourcing or sharing your experiences through the federal register because it's really important for us to hear this.

So let me turn back to the phone and see if we have Rochelle on the line?

CALLER ROCHELLE: Yes.

MS. BENT: Rochelle?

CALLER ROCHELLE: Hello? Yes.

MS. BENT: Finally. Success. Right. Sorry for all of the phone glitches.

CALLER ROCHELLE: Oh, no worries.

MS. BENT: Please go ahead.

CALLER ROCHELLE: I just wanted to say that I'm 56. And I've had vitiligo since I was 25. And just like what Alicia was saying in Georgia, it's pretty much the same kind of stories that everyone else has gone through.

But just recently, we had a flood, and everything happened to our house. And we just had to have a restoration team come in. And these two guys came in, and they were -- you know? -- looking at the house and everything. So my husband was showing them the carpet and so forth. And then I came in, and they were asking us to sign something. I said, "Well, I can't sign it. Let me call the insurance company." So when my husband went back out there and was talking to one of the guys who was just playing with one of our dogs, and the other guy was gone. And so he said, "Well, hey. Man, where's your partner?" He said, "Oh, he's outside. He doesn't really feel comfortable with you being black and your wife is white."

And all these years, I mean, I thought I had it pretty much together. I do run a support group here in Virginia. And you know? I talk to other people, and I'm pretty comfortable in that. But for that moment -- you know? -- it's like I'm not. I mean, but the guy started justifying. He said, "I think they're pretty. A lot of fine black people in the world." So it's like a different kind of racism, and it was just really upsetting. And I couldn't believe. I said, "After all these years, that hurt my feelings," because he didn't want to come in our house because that's what it was.

So it seems like that that I've been dealing with and like what other people are saying with the kids. And I have two sons. And when they were younger, and that’s what people would say, "Is that your son?" "Yes." "It's him right there?" "Yes." "The one in the red shirt?" "Yes." I said, "The one with the brown face, yes. That's my son."

And you know? You're trying not to be so frustrated, so I kind of try to find a little humor in some things to try to help me cope. Not to cover but just to cope. And it seemed to kind of lightened the mood when you could talk to people about it.

But I did try that PUVA treatment years ago. And it worked for me, and I had like 75 percent of my body was depigmented. And then it all came back with the PUVA treatment. But then I ran into a problem with my insurance company. And the insurance wouldn't cover it because the coding looked like it was for psoriasis, and when they found out I was taking the treatment, then that's when it all messed up. Then I lost it all again. So that's a struggle to go through that. It's hard on your body. And I don't know if I would do that again. But I just wanted to share that with you.

MS. BENT: Yeah. Thank you very much for that. I'd like to turn now to one of our panelists, Alicia. I will tell all of you who are watching online that your stories that we're hearing today are really impactful and really profound. And I think that Alicia just wants to briefly kind of touch on the existence of support groups and things like that. So let me turn to her for just a brief moment.

Go ahead, Alicia.

MS. ROUFS: Hi, everybody, again. I just wanted to mention the amazing support community our vitiligo community has. And this is something that has been slowly in existence for the last decade or so and really has taken a huge push in the last five to six, seven, eight years. And it really has brought our community together and has brought us here today to the FDA. And that was through the support that we have for each other.

And so any of you guys that are watching this that aren't on the panel that are looking for support, there are so many great places to go to. So just check Facebook. Check Google. And check out support communities. And we will reach out to you and bring you guys together. There are great resources for kids now that I never had growing up. Great resources for parents and people struggling day-to-day with vitiligo. So you are not alone in this. We are here for you. Please reach out. And thank you to the FDA for doing this too to bring us all together.

MS. BENT: Thanks, Alicia. And when your mentioning of kids, I kind of wanted to maybe to take a moment and circle back a little bit to Dr. Marcus's question, which was really trying to understand as people are, particularly, when you're younger and -- not that it's different as we age. But when you're younger, kids can be a little bit more harsh, I think, than adults sometimes. And so I think what would be helpful for us to understand is would your younger self -- I guess for lack of a better term -- be willing to kind of take a different amount of risk for an effective treatment than somebody's who has been living with vitiligo for a longer period of time and kind of come to a degree of acceptance with it. So let me see if there's anybody who has any thoughts on that before we turn back to people on the phone. Is there anybody that might want to speak to that? And of course, as everybody is aware, we will be kind of getting more into that impacts of treatment in Panel Two this afternoon after what I will call lunch. Depending on where you are, it might be something different. Go ahead, Alicia.

MS. ROUFS: Yeah. And I was telling Dr. Marcus this too. I think with the risks of being a child, what was hard for me when we looked into doing treatments was the frequency that we would have to do them in the doctor's office. So light therapy is something that is seen as probably the most effective treatment along with creams, and we had to go to the doctor's office three times a week to do that. And not having it in town, the cost associated with it, and the time spent, I think is what a lot of people just don’t do.

So as children, when you're running around and you're in all these activities, who has time for that? So I think if it's something that we can have at home that we can do ourselves, yes, there are always risks in any kind of treatment you do. And so knowing those risks and being able to accept those risks if you're going to see results, I think a lot of people would willing to do that. But I think for most of us in the vitiligo community, having it not take so much time and so much money is key.

MS. BENT: Thanks. Let me go to Mark now.

MR. BRAXTON: Yes, I just wanted to add quickly that when we look at our youth and our students, I think a big component is education. We have to not just teach our children how to accept kids with differences or adults with differences; we have to teach our adults as well. And I think the big difference between our generation and the kids' generation, I feel like our kids are more about inclusion. They support each other. They like to include.

But I think in our generation, anyone who looked different, whether it's a condition, skin, whatever, we kind of balked at that. We kind of standoffish, or we treated them differently as other have put it like monster sometimes based on how you look. But I think our youth are at a point where they are more understanding than we think so. And we need to give them credit. They do understand. And also they sometimes teach us as adults how to treat each other, and I think a lot of it starts with our elementary school kids. Teach them there how to accept -- you know? -- our conditions and other conditions.

And as they become adults, I think they'll have less issues. But also -- you know? -- let's look for ways to provide treatment to our youth for our kids that need it or that want it. And I think a lot of times the want comes from the parents because they want the kids to move about normally like everyone else, or what we consider normal. Thank you.

MS. BENT: Thank you. Let me turn briefly to Sharon, and then we're going to go back to the phone lines. Sharon?

MS. KING: Thank you. I absolutely think that if there were more options and there was more information in 1999, I would more likely than not explored other ways to treat my vitiligo. But at the time -- you know? -- I just made the basketball team.

As Alicia said, we're doing all these activities. And my mother was a big advocate when I said I didn't want to do it. That was just it. You know? And I think that sometimes -- you know? -- like Mark said parents do get caught up in that and not wanting their children to be ostracized and things like that.

So I absolutely think if there were better options, more options, options that weren't just medical, I definitely would have engaged more in some type of treatment or some type of support. As Alicia said, there wasn't a lot of information back in those days where you see now everything is inclusive. You see vitiligo everywhere in the mainstream. Everywhere. So you don't feel as alone as you would have -- you know? -- back in our day. So yeah. That's what I got to say.

MS. BENT: Thank you. That's helpful, and I think we have made some progress. I think that that's really very encouraging.

So let me turn now back to the phones. And I think we have Kathy on the phone? Hello?

Hello? Hello? Okay. So maybe we'll put Kathy back on hold for a moment and go to Makayla [ph]?

CALLER MIKAEL: Hello. This is Mikael [ph] from Iowa.

MS. BENT: Hi. If you could share your experiences with us for just a minute or two, we would really appreciate that.

CALLER MIKAEL: Sure. I am 35 years old, and I have had vitiligo since I was two. I have universal vitiligo. So I'm completely depigmented. And I just wanted to say that once you have universal vitiligo, I feel like a lot of dermatologists think that you're fine. And I would like to say that it's not over when you're completely depigmented. Like you still have the effects, for me, childhood. The emotional effects. And then also I worry about my children. I have a son who has vitiligo and thinking about having more children really worries me because I already have on that has vitiligo. And there really aren't many treatments for my son. The ones that he's doing right now are the laser treatments, and he has to go three times a week. And he doesn’t like having to do that three times a week as an 11-year-old.

So treatments that we could do at home would be awesome, and more options would also be great. And then also the depigmentation of hair is a big thing for me having universal vitiligo. If there were any treatment options for that, that would be wonderful.

MS. BENT: Great. Thank you. Let me turn now to Terry on the line. Terry?

CALLER PERRY: Hello.

MS. BENT: Yes. Hi.

CALLER PERRY: Hello. Is this me? I'm Perry actually if that's who you're mentioning?

MS. BENT: Yes. Yes. That's who I'm looking for. If you could share your experiences in just a minute?

CALLER PERRY: I'm Perry from Philly. The main thing I want to say is it's important for vitiligo sufferers to find the right dermatologist. I didn't at first. Very briefly background. In my 40s, I had a very small spot. Once I got over 60, it exploded. And it exploded literally overnight. One morning I woke up, my forehead was gone. One morning I woke up, I had spots all over my arms.

So I went to the dermatologist that I had used for years for relative sort of matters to treat me with creams and never mentioned that there was such a thing as UVB treatment. Never mentioned it for two or three years. I was just treated with the creams. And one day, she said, "Well, you probably would be a candidate for having all the pigment removed from your skin because it's pretty pervasive, and you haven't responded to the creams."

Well, I knew I didn't want to do that. So I looked things up on the internet, which unfortunately I'd never done before. I found a dermatologist that had UVB treatments. I went in there, and within five minutes, she said, "Why haven't you been getting UVB treatment?" And I said, "It's never been offered." So I began to have that. And it's still kind of -- but it does provide very gradual results. In my case, it does shrink some of the spots.

But I went to a dermatologist, and this was no hole in the wall dermatologist. This was a respected mainline Philadelphia dermatologist who withheld knowledge of a certain type of treatment either because she didn't know about it or couldn't do it. So I just want to stress the point that it's important to -- if you're not happy with your dermatologist, look further. Because I never would have thought to have this.

God forbid I'd have cancer, and she'd withheld treatment. So very important. And I want to make sure that all your listeners know that. Don't settle for somebody who doesn't know what they're doing.

MS. BENT: Right. I think it's universally important to find a care provider that you're comfortable with. Thank you for that.

I know we're going to be wrapping up the session. In fact, we're a few minutes over. Let me get one more person from on the line before we wrap up this session. Would that be Terry? Okay. Hello?

CALLER TERRY: Can you hear me?

MS. BENT: Yes, I can hear you. Please go ahead. I would ask you just to keep your comments relatively short because we've kind of run over in this session, but we do want to hear what you have to say. So please go ahead.

CALLER TERRY: Okay. So my name is Terry. I'm calling from Atlanta, Georgia. I'm going to keep this very brief. This about the FDA and vitiligo. Okay. Basically, FDA knows a lot of information in reference to diseases and everything else. The reality here is that the FDA just needs to pay attention to vitiligo. We know at this point in time there is no really known cure for vitiligo, and I've heard the whole calls all morning. I've heard the calls and the concerns of people. There's only one reality. It's that the FDA is going to cooperate with the vitiligo community in reference to treatment or other things that we need. And it's really just that simple. So FDA, the topic of discussion today is working with the patients. We need your support in every area of treatment at this point. And it's really that simple. FDA, you have enough resources to study vitiligo, and at this point, there is no cure. Research and money will help the situation at this point. And it's really just that simple.

MS. BENT: Thanks so much, Terry. Appreciate your comments. So now at this point in the meeting, I'd like invite all of our panelists and discussion starters to just turn on their cameras for a brief moment, just so that we can really say thank you to everybody for the really important, insight, and impactful comments and thoughts they've shared throughout our first session. I can't tell you how much we very much appreciate all of you sharing this information. And I really hope that this will really make others understand what people living with vitiligo are experiencing. I also want to take this opportunity to thank people who have submitted comments and called in. So thank you all. Really appreciate it. And we're going to now take a break until 12:45 Eastern time, where we will come back and kick off session two. So thank you all for taking this time to be with us. And we'll see you at 12:45 Eastern. Thanks, everybody.

(Off the record.)

MS. BENT: Welcome back, everybody. I hope that you had a good break. There might be some noise on the line. So welcome back, everybody. I hope that you had a good break. We have limited time. So we're going to go straight into Topic Two.

As we mentioned, Topic Two will focus on current approaches to treatment of vitiligo, your experiences, and your perspectives on that, what you'd like to see in an ideal treatment, if future treatments could be better, how could they be better. And we have five panelists who will start off our discussion by sharing their experiences. Before we launch into our panelists' experiences, I want to let you know that our first question for the open discussion question is going to be: what are you currently doing to treat your vitiligo; how has your treatment regimen changed over time and why; and what symptoms would you like to see most improved or resolved by treatment?

So we're now about 30 minutes away from people sharing their answers. But if you're interested in responding to that question, please consider sharing via the internet or by calling the 1-800-527-1401 in about 30 minutes. I'd like to welcome our session two panelists and thank them for joining us today. I'm going to start by inviting Jamila to share her experiences with vitiligo. Jamila, if you'd like to turn on your video and unmute?

MS. CHOWDURY: Yes. Hi, everyone. My name is Jamila. I'm 18 years old. And I'm here to talk about my experience with vitiligo. The first patches to appear were on my face, specifically around my eyes when I was around eight years old. It was alarming to say the least for something to appear seemingly out of nowhere. It's been around 10 years since my diagnosis. I have tried various methods of treatment and other forms of interventions for my vitiligo, including topical treatments, laser treatment, homeopathic remedies, and makeup.

In the beginning stages, I developed patches on my knees, elbows, underarms, and a tiny spot on my neck. Certain areas of my body developed vitiligo later on in life, such as a small spot on my ankle, my chin, behind my ears, and a little patch at the tip of my nose. I have used prescription ointments, such as Protopic, and excimer laser treatment, as soon as I was diagnosed.

Applying the ointment was very tedious and not something I did frequently because of the sticky texture. I had a more positive experience with the excimer laser. I would go to the dermatologist weekly to receive treatment on all areas of my body that had vitiligo. The most responsive were around my eyes, my knees, my elbows, my underarms, chin, and neck. The spots around my eyes and neck have disappeared since receiving treatment. The pigment came back in little spots, and occasionally I would experience a bit of burning, irritation, and peeling due to the high heat of the laser treatment.

The next time that I would return to receive treatment, the strength of the laser would not be increased to prevent burning. However, other than the rare and mild irritation, my experience with excimer laser was overall positive. It wasn't always convenient to get treatment as my schedule got busier. I wasn't able to commute to the clinic as often. Eventually, my schedule no longer permitted me to get weekly treatment, and today, I no longer receive treatment after being treated on and off since my diagnosis.

I'm open to being treated again. And in an ideal treatment, I think it would be best if it was a medication that I could administer on my own at home and is cost effective. I'd be okay with mild side effects if the results are promising. I look forward to future discussion about vitiligo, and I'd like to thank you all for taking the time to listen to my experience and for giving a platform to share our experiences. Also to my fellow panelists, thank you for being brave enough to share your stories.

MS. BENT: Thank you so much, Jamila. I'd like to now turn to Priyanka [ph] and Vimla [ph]. They are going to share their experiences together as mother and daughter.

PANELIST VIMLA: I want to start off by thanking the FDA for giving Priyanka and me this great opportunity to share our perspectives, not only as a patient but also as a caregiver, and join our voices with the rest of the vitiligo community today. It's been a fantastic experience so far.

So my 15-year-old daughter Priyanka who's here with me today had her first onset of segmental vitiligo at age 12. The diagnosis was not straightforward, and the treatment options were few, onerous, very expensive, and not easily accessible. Priyanka's treatments over the last three to four years focused mainly on repigmentation, and that included both surgical as well as non-surgical options, which really were topicals, light treatment as well as many punch graft surgeries.

The treatments ran a long course and failed to yield optimal clinical results while the vitiligo continued to ravage her body, spreading from her face to the neck, shoulder, arms, and the back. I will say that our journey was a very frustrating one because the rate of progression of a segmental vitiligo was significantly greater than the few specks of repigmentation observed. Overall, the disease and the treatments have resulted in debilitating side effects with a dire impact on her physical, emotional, and psychological health.

Priyanka has also needed to gradually shift her treatments as well as treatment regimens due to the lack of immediate response. She actually started with topical creams, such as triamcinolone, every day. And then switched to a combination of tofacitinib in combination with tacrolimus on weekends. She then switched to a combination of topical treatments with light treatment, which last for three years at twice a week frequency.

Most recently, since the start of the pandemic, she has started using the handheld DermaPal unit for light treatment. Overall, the side effects of the light treatment were many, ranging from severe skin inflammation, redness, itching, photosensitivity, burning sensation, blistering, and pain. Two weeks ago, she actually had a chance to have a mini punch grafting surgery and experienced residual pain in the grafted areas.

Today, we honestly see the FDA's support as well as the medical community's support to universally recognize vitiligo as a medical condition and not a cosmetic condition to spur new treatments for all patients. We also would love to get support on providing more effective oral, topical as well as injectable treatments, advanced surgical options, and improved light therapies that permanently repigment and have limited side effects. There was a panelist who also alluded to this exact point in the morning session. So we'd really love to see advancements in this area. And lastly, I'd say, we'd love support on global scientific research as well as clinical trials with broad patient populations including children.

With that, I want to thank you very much again for this great opportunity. And I will now pass on it on to Priyanka, so she could share her patient perspectives. Thank you.

PANELIST PRIYANKA: Hello. My name is Priyanka. And I'm here to talk about my vitiligo journey. So my vitiligo journey to date has been a very difficult one, ranging from shock, disbelief, and frustration to education, advocacy, and sharing of my vitiligo experiences with the community.

As I have a darker skin tone, my noticeable vitiligo draws the most attention from others with unwanted stares, disgusted looks, and unspoken questions. Returning to school post-treatments was painful with blisters, caked ointments on my skin, a sore face, and extreme discomfort from clothes chaffing against my treated skin. And my recent punch grafting surgery wasn’t exactly an easy experience either.

I used to swim, bike, skateboard, play the violin at concerts, and manage track and field at my school. But due to my vitiligo and the painful side effects of the treatments, I cannot practice the violin or participate in performances, meetings, or social gatherings as much as I would like. During the pandemic with remote learning, I am always off camera on Zoom to avoid prying questions from my peers. And this impacts interactions in class and hinders my level of learning. I have also been the only kid with vitiligo in my entire elementary, middle, and high school, which makes me feel often very isolated.

The impact of vitiligo and the lack of treatments to limit disease progression has burdened me psychologically and emotionally and stigmatized me socially in ways that I cannot adequately explain. At a time in my life when I was ready to explore the world, learn new things, and have fun, vitiligo chipped away at my morale, self-esteem, confidence, and quality of life. I know I'm not alone in this journey and request the FDA to help advance better treatments and cure for this disease. Thank you.

MS. BENT: Thank you so much both, Priyanka and Vimla. We're now going to turn to Lee to share his experiences. Lee, if you'd like to turn on your video and unmute?

MR. THOMAS: Okay. Can everybody hear me?

MS. BENT: Yes.

MR. THOMAS: Okay. I'll try to keep my comments brief because I can talk a lot. So let me start off by saying my name is Lee Thomas. I've had vitiligo most of my adult life. That's almost 30 years. I've had pigment come back in about 80 percent of my body and then go again, which is something that I really was not expecting. I've also spent most of my adult life in the public eye. I'm an anchor reporter, and I wrote a book about my disease, about my struggle, and I got the opportunity to tour the world sharing my story, which was honestly quite difficult but necessary I felt.

And I'll share a quick story. I was on a plane. I was next to a guy. He seemed like he was doing very well. We had a good conversation. The plane's getting ready to land. And the guy says to me, "No offense. But are you a black guy? Because if you're no longer black, then what are you?" So I'll answer that question and ask it again. I'm a black man who's had many attempts at trying to stay black honestly. And I tried everything. Everything that I could afford, I tried. I tried steroids. I tried inhibitors. I tried PUVA. I tried laser, excimer laser. I tried every light treatment that was suggested to me by whatever doctor I could get in front of until I found the best doctor that I could find.

For one year of my life, I would do the morning show here in my city. I would take off my makeup. I would drive to the hospital, stand in front of a light completely naked, three times a week for about one minute, and then I'd have to put my makeup back on, go back to work, and finish my reports for the day. I would squeeze it right in between the morning show and the noon show. It was very difficult. It was unsustainable. It was not affordable. And I could not do it. I tried every treatment that our country had to offer.

Now I stopped 10 years ago. But after the book, I found myself in Russia on a panel with government officials, with doctors, with drug companies. And that made me very hopeful. That was a decade ago. It seemed like doctors weren't sharing their information a decade ago, but they are now thanks to Vitiligo Research Foundation, Global Vitiligo Foundation. I love those places.

But the best treatment I found was in Germany. It gave me 80 percent of my pigment back. I want to show everybody what that looked like. It gave me a lot of my pigment back. This is me. My face was about 60/40 there. I had to wear makeup to be on TV to do my thing. But it was the most successful thing I found. Dr. Schallreuter is her name. But as you can tell, it has gone again. And I don't know what it's going to do. Summertime, sometimes it gets better.

I'll leave you guys with this. One question stood out on the survey I was sent. It was about a particular body part. I'll read the question. "Is there a particular body area affected by vitiligo, such as face, body, that you would prioritize for treatment?" And that question made me laugh because it's like picking your favorite kid. But I get it for clinical purposes. I understand. And my answer is I would love to have my face back. I was born a black child. I'd like to die a black man. I don't know if that's ever going to be possible for me.

But it's important for me to represent people with vitiligo. Hopefully in my lifetime, they'll be an affordable treatment that everybody can have in our country. So I guess, I will end by saying I believe in this process. I believe in the FDA, the doctors, the many support groups, including the one that I'm a part of. Be Strong. All of the support groups.

And if there's a drug that in development or a treatment that's in development, I'll leave everyone with this question. And the question is quite simple. It is. What are you? And to me, this entire group, this entire process, is what are we. And hopefully, we can be the beginning of the answer.

So thank you for giving me the time, FDA and everybody else. I appreciate it.

MS. BENT: Okay. Thanks so much, Lee. Really appreciate that. We're now going to turn to Carrie and Bella to hear their experiences. Go ahead, Carrie and Bella, whenever you're ready.

MS. C. GUARINO: Thank you so much for giving us the opportunity to speak on behalf of myself and Bella and the many teens impacted by vitiligo. Bella's also a member of a teen support group called Purple Patch Teen, a part of VITFriends. That's had a huge impact on her recently and helped her so much. And I just want to share that a lot of what Bella's going to be talking today is representative amongst the group as well.

But I thought I'd give an overview of Bella's journey with vitiligo and then turn it over to her to talk more specifically about the treatments and her experiences with them. So Bella was diagnosed with vitiligo just shy of her 13th birthday. I remember doing her hair and noticing some white spots behind her neck. At first, we thought it was tinea versicolor, which is often confused with vitiligo. And it was confirmed that she did have vitiligo. Over the course of about a year, her spots traveled from her neck to other parts of her body, including her knees, her chest, her back, her armpits on both sides, and eventually her face.

And she started out taking or using tacrolimus monotherapy as prescribed by her dermatologist. And she was using it on all of the different spots for over a year and had very little effect. And when the vitiligo ended up traveling to her face, we sought some different treatment from a specialist, and he prescribed more aggressive therapy that included combination phototherapy with some other creams. And I just want to emphasize before I turn it over to Bella that the process has been quite laborious. It's been extremely challenging. It's been lengthy. Just the treatments. The process of it. Burdensome. Just emotionally and financially.

Bella has had treatment success as you can see her face. I did send in some pictures. I'm sure they'll be on the presentation at some point later. But her face has repigmented, but it's taken a lot to get there. And we just wanted to emphasize, again, that the journey's not been easy. So I'm going to turn it over to Bella to take you through the treatments starting out with her experience with tacrolimus.

MS. B. GUARINO: Hi, everyone. I'm Bella. I'm 16, and I'm glad I'm able to share my vitiligo journey with you guys. So as my mom said, first, I was prescribed the tacrolimus ointment. And I used that twice per day, and it really wasn't very effective either. I was on it for about a year, and I saw really very few results. And there were a lot of other side effects as well. The ointment was very greasy, and it often made me break out a little bit, which I wasn't expecting. And there were like red bumps, and it really wasn't a nice ointment to use.

So after about a year on that ointment, my doctors prescribed me with another topical steroid to use in addition to tacrolimus. So I used both of those together twice per day. And we also started phototherapy in addition to those two ointments. We used phototherapy three times per week, and I'm very fortunate. I do have a phototherapy unit at my house. My parents and I thought it would just be more efficient than having to drive to the dermatologist three times per week for like two minutes in a light box.

So the phototherapy I'm going to talk about for a little bit because I thought it was really important and a big role in my vitiligo journey. So phototherapy really helped. It's supposed to make your vitiligo spots a little bit pink so that they can repigment. But there were a few other side effects that you have to be aware of when you're going through a phototherapy unit. One of them is that you have to wear protective eye goggles. And an issue that came up for me was that I did have a vitiligo spot on my eyelid. So we had to weigh the risk benefits of going in wearing goggles versus not wearing goggles. So we actually decided not to wear goggles.

My doctor actually suggested I put a pillowcase on my face midway half in because another thing we were coming across was that my face was getting very, very red. And it was very sensitive to the light. And my vitiligo spots weren't really getting the things that they needed in order to repigment. So we were kind of shocked by him saying that I should put a pillowcase on my head.

MS. C. GUARINO: Yeah. There were barriers to treatment, and different things we had to play with.

MS. B. GUARINO: Right. Yeah. So I think that we just had to play around with a little bit to see how long I needed to be in there without my face burning and the with the other spots getting pink. But it did really make a big difference in my journey.

The most recent medication that I've been on right now is ruxolitinib. It's a topical cream. I just started it a few months ago. I think it's really the most effective aside from the phototherapy right now. The issue is that it's extremely expensive. Like the small tube that we have is $350. So you really have to prioritize how you use it.

MS. C. GUARINO: Right. Bella's doctor had -- I think two weeks into the treatment, she had used up the little bottle or the little tube, and at that point, we called the doctor. And he said you really just need to choose which spots you want to use it on because we can't be refilling the prescription every two weeks.

So Bella's given you kind of a glimpse of her journey. And obviously, there's so much more that's gone into it over the last three years. She's 16 now. She has had success. However, it's not come without a lot of challenges on a daily basis, and just a lot big -- in terms of time commitment, creams, side effects, emotionally, physically. You know? Just so much has gone into it.

And I think one of the things that she and I talk about Bella's relied so much on the phototherapy unit to keep her vitiligo at bay. The concern that I have and that we talk about moving forward is you can't take a phototherapy unit with you to college. And she'll be going off to college in a couple of years. And so we have some anxiety related to the challenges that go along with treatment when Bella leaves our house.

So anyway, thank you so much for the time you've given us to speak today and hearing Bella's story. And we hope that the FDA and that companies can come up with further treatments that'll simplify the whole process.

MS. BENT: Thank you so much, Carrie

and Bella, for sharing your experiences. And your story having to choose which spots to put the ointment on or the creams on kind of harkens back to what we said about having to choose your favorite child as far as choosing the spots. So I think that that is probably a theme that we're going to hear quite a bit today.

So moving on. Stephen [ph], I see that you have turned on your camera, and you're unmuted. So if you wouldn’t mind sharing your experiences, I would really, really appreciate that. Thank you.

MR. TAYLOR: Thank you. My name is Steve Taylor, and I am a 61-year-old retired Afro-American with vitiligo. Since being diagnosed in 1982, I tried various forms of treatments. For example, I tried different light treatments, different topical medications, and off label products to name a few. When my dermatologist first diagnosed me with vitiligo, the initial outbreak was in the hands and elbow area. And he pretty much said in so many words there is no cure or treatment for this disease. I said no problem. I accepted it as fact. Moved on with my life. I pursued professional counseling, support from my wife. And I made pact with myself. As long as I don't break out in the face area, I'll deal with it.

Well -- virtual connectivity interruption -- break out on the face. And because of that, I sought after a second opinion. Now this dermatologist was more knowledgeable than the previous one because he prescribed a Protopic medication for me to apply on my face. Now I didn't apply it apply below the neck because the spread of vitiligo was too large of an area to treat. And for the most part, the ointment did prevent the face part of the application from getting worse.

The following year, my dermatologist mentioned to me about a new photochemical light treatment called PUVA was now available. I was excited. I said, "Yeah. Sign me up." So for the next six months, I traveled three days a week, a two-hour roundtrip visit to the University Hospital in Ann

Arbor, Michigan. I go into this full light treatment process, ranging from 15 seconds to 20 minutes at most. And that's all the treatment I had.

Now about two months into the treatment process, the stress kicked in. Time, travel, gas, leaving work early, unforeseen circumstances. And did I mention that this was a stressful period in my life? However, halfway through the treatment process, I began to repigment, especially around the face. That was the shot in the arm I needed to stay focused and true to the course.

Now at the end of the six months, my dermatologist and I did a risk benefit assessment. And I decided to discontinue treatment because the risk outweighed the benefits. That is to say the potential side effects, premature aging of the skin, skin irritation, skin cancer, cataract, not to mention the continued stress of moving forward with the next phase of the PUVA process -- and just a side note, I did try UVB light treatment but to no avail.

So in summary, I am 98 percent void of

color. And I am no longer taking any treatments. And why? I'm still dealing with the emotional stress of the loss of my color. My identity. And I do not want to go through this process again unless there is a cure and not a treatment. In conclusion, I'd like to thank the Food and Drug Administration, all of the dermatologists, all of the researchers, all of the pharmaceutical companies, and all of the vitiligo support groups worldwide working unitedly for the cure. Thank you.

MS. BENT: Thank you so much, Steve. Really, really appreciate that. So once again, these are some really compelling and diverse experiences. And I thank our panelists, Jamila, Priyanka, Vimla, Lee, Carrie, Bella, and Steve, for sharing them.

I'm now going to take this opportunity to introduce our discussion starters. So at this point, I would like to invite Jay, Beverly, and Mary to turn on their cameras. As with the discussion starters for Panel One, these great people have agreed to kick off our discussion by answering some of our questions. I'd also encourage if our panelists have thoughts that they might want to share, we'd be happy to hear them as well, although we are planning on going to some of the people that we have waiting on the phone as well.

So as I mentioned before, these are our discussion questions for Session One. And our first discussion question is, "What are you currently doing to treat your vitiligo? How has your treatment regimen changed over time and why? What symptoms would you like to see most improved or resolved by treatment?" So I'm wondering maybe if I could turn to Jay. Jay, would you be willing to kind of take a first answer at the question of, "What are you currently doing to treat your vitiligo? How has that changed over time? What symptoms would you like to see most improved?"

MR. HAMPTON: Yes. Thanks for the panel, and the FDA for giving this opportunity to me.

MS. BENT: Thanks, Jay.

MR. HAMPTON: I mean, I've been doing

treatments since I was -- what? -- 15. I'm 34 right now. And currently, as I'm talking you, I'm not doing any type of treatment at all. Yeah, back when I was 22, my dermatologist sat me in his office, and he essentially said -- like I'm sure other people that take treatment as well -- he said, "Jay, there's really nothing else I can do for you." And that was like a shot in the gut for me because I was really gung-ho on this whole experience.

But with me, though, I did take the PUVA and the light treatment. I'm from Baltimore. I don't know if you know anything about John Hopkins Hospital and University. Very research hospital. My dermatologist was from there. They do a whole lot of types of experimental treatments for me. And one of the ones that proved very effective was the suction therapy. They took this this suction machine and placed it on my forearms. And they sucked up the stem cells in hopes that they'd take the stem cells and implant them in my face. And then when my skin would heal, I would use light treatment, and that would spread pigment on my face. So what you see my face now, my whole face had vitiligo on my scalp, back of my neck. And it's come back.

But I will say that sticks out the most when I was taking that PUVA treatment. I had to take three horse pills. I'd go three times a week. And if didn't have nothing on my stomach, it was like death taking those pills. Very, very nauseating. Very uncomfortable. And I was a teenager at the time. You know? So you always have crackers because sometimes I wasn't able to eat nothing when I had to take those pills, but I'd stroll up on time for my appointment.

So that's basically what was my experience with it. But to be honest with you, with the light treatment in my mind, I'm thinking, "Okay. There's UVA light and UVB light." And sometimes when work I out and I go to the gym, I go to the tanning salon. You know? And I know the light that that is. But in my mind, I'm thinking it's doing something because it's darkening my skin pigment-wise. It's a proven fact of somewhat because my skin gets darker, and it kind of contrasts my light spots. So I don't know if that's bringing it back. I don't know if that's my mind. But I'm just trying to find different things I can do in the interval.

MS. BENT: Great. Thank you. That's really helpful to hear. Let me take a pause now from talking to our panelists and turn briefly to the phone. Let's go to Line 2, Kay from Maryland.

CALLER KAY: Hello.

MS. BENT: Hello, Kay.

CALLER KAY: Hello. Can you hear me?

MS. BENT: Yes, we can hear you.

CALLER KAY: Okay. Thank you. Thank you for this opportunity. So my story's no different from other people, but age 48, I saw white spots on my hands in September 2019. Not long ago. Soon after that, I was diagnosed with vitiligo. And vitiligo is spreading fast all over my body. Now I look like I almost lost more than 75 percent of my color.

So one thing I want to mention here first is the first dermatologist told me, "Oh, you have vitiligo. It's just nothing. It's a cosmetic problem." He just dismissed all my concerns. And that really painful because it was really affecting already the psychology. The most difficult issue I have now is the itchiness. It can itch me anytime, mostly on my back, in between my legs. It's very irritating. When I take a shower, it's feels better. And that's one problem I have besides the psychological impact. I've tried everything. I used multiple creams, light therapy. I used to have the light treatment three times a week. I tried it about six months. Nothing changed. I tried oral steroids. I tried topical steroids. I tried everything. And at the end now, I decided, especially with COVID, I don't want to deal with this. I have other things. I try to forget, but still, it's in my head. I am doing nothing treatment-wise because I gave up. We don't have anything further -- because it seems like nobody can see there to begin with that this is a problem. They think it's cosmetic, but it's more for me. I am lifelong colored person. I feel like I lost my identity. I'm sorry. It's very difficult to be so emotional.

MS. BENT: It's okay. We understand. These are emotional topics.

CALLER KAY: Yeah. Yeah. Sorry. After I tried everything, I decided that I don’t want to have any more problems. I already have enough problems. So let me just deal with the psychology. I used to start seeing a psychologist. There's no drug for this monster. Just ripped my confidence, my coloring, my identity. I really wish they'll be something else for me. I am 50 years old now. For the young kids, we need somebody to understand and consider this as it is a problem. And I -- for my -- this is like disparity. It's one with a disparity. It's mostly affects colored people, and it's more visible on colored people. Hasn't been considered as a problem. And I want the FDA to consider how much the impact of vitiligo on our mental health. For 49 years, healthy person being now, I don't want to go outside. I don't want to see my face in the mirror.

And thank you for the opportunity and sorry to be emotional. Thank you.

MS. BENT: No. Thank you, Kay. And I think that we've heard from a number of people the challenge that vitiligo adds to their identity. And it certainly seems to be very, very impactful.

So let me pause for a moment and turn to Shannon to see if we have any comments from people online. Shannon, do we have comments?

MS. COLE: Yes. Thank you, Robyn. We have several comments from webcast participants, mainly, talking about their current treatments.

One said that they are currently using tacrolimus and excimer therapies. Another one said that they are seeing improvements from the excimer laser therapy. Another participant stated that they're using fluocinonide, Elidel, and UVB light therapy. And after five months of sticking to a strict regimen of using the UVB light and creams, they've noticed about 75 percent repigmentation. Another participant has used topical ointments and stated that they even tried a liquid medication that's not prescribed in the United States. But it did help for them to gain back some of that pigmentation, but they stated that it's been difficult to continue that medication since it's not available in the US.

We also have some participants who have used PUVA, and it was effective. But they stated that they needed a break from it because of the side effects and the treatment regimen. And we also had one more who has used NUVB and tacrolimus vitamins and stated that their face is most responsive to the NUVB and tacrolimus. And their hands and ankles are virtually impossible to treat with the available methods that they have tried.

MS. BENT: Thank you so much, Shannon. So we're going to now move onto some polling questions to get feedback from all of you who are joining us online. Polling remains limited to participants who have lived experiences with vitiligo. If we can go to the polling question, this is just to kind of start the discussion.

Polling question -- I guess technically it's number nine, but I don’t feel like it is. Have you ever used any of the following medical products? And this would include drug therapies or medical devices or interventions to treat your vitiligo. And the first option is topical medications for repigmentation, such as corticosteroids or immunomodulators, which would include Protopic or Elidel. Oral medications, again, such as prednisone or other steroids or other immunomodulators. Light therapy, such as laser, phototherapy, or PUVA. Surgery, including grafting, melanocyte transplants, or micro-pigmentation. Topical medications for depigmentation, such as benoquin. Other medical products or interventions not mentioned. Or are you not using any medical products or interventions. And this not using any medical products or interventions would be never used medical products or interventions.

So all right. Looking at the results, and again, there is a bit of a delay between when we ask the question and when it kind of makes it out to the frontend for people to respond to the question, but it does look like we're seeing a large use of topical medications as well as light treatments. The first blue block is topical medications. The green block that's showing at about 31 percent are the light treatments, and the final 9 percent at the end kind of the far right or 8 percent -- it's changing as I speak -- is not using medical products or interventions and never used medical products or interventions.

So while we're waiting for these polling questions, I wonder if we can start with one of our discussion starters. Beverly, I wonder if you would be willing to speak to us a little bit about what kind of treatments you've tried and what aspects they addressed and what aspects they didn't address and maybe how your experiences with them have changed over time?

MS. SMITH: Yes. Thank you so much for having me and this discussion with the FDA.

When I was first diagnosed with vitiligo in 2015 at the age of 67, I was immediately given the Protopic. I was also given the photo light treatment where I went three times a week in a full body chamber for photo light. I did that for about two and a half years. And I really didn't see a lot of progress in either one of those treatments, even though the dermatologist took photos and kind of said, "I see a little more pigmentation here and a little bit more here." But I don't know. My vitiligo just progressed and was so aggressive. I didn't see any progress at all period.

So after about two and a half years of going three times a week for the photo light therapy and using the creams, my medical started not to cover the visits because they said it was cosmetic. So I wasn't able to pay for those three times a week treatments on my own. So I kind of discontinued the treatments. But for me personally, I didn't see any effect of the photo light or the creams. So I just stopped using all of them and just let the vitiligo progress as it would normally do.

So right now after about six years of

vitiligo, I'm just about 85 percent covered with vitiligo. So I do hope for the children who are on the panel, the young people, that we can find some kind of cure or a more effective treatment, so they wouldn't have to live their whole lives with vitiligo. I'm very fortunate to only have had vitiligo for six years. I'm 73 years old right now. And I have not had any problems with my vitiligo at all period. I am fortunate to be in a great group with Lee Thomas and Stephen, Be Strong support community. Folks are very, very helpful in all aspects of vitiligo. So we really need treatments that are more effective than what we have already.

MS. BENT: Thank you so much, Beverly. Let me now turn to maybe the phone. Line 2, Kay, to maybe speak to thoughts about treatment and what you look for in an effective treatment. Sorry. Line 3, Anna. Hi, Anna.

CALLER ANNA: Hello. Hi. I'm glad to be here. Thank you for doing this. It's exciting. I am here today. I have had vitiligo for over 40 years.

I've tried millions of treatments from all over the place. And my daughter also now has it. She's had it for about 11 years. And our most successful treatment is with the German treatment, the pseudocatalase, in Germany and Jordan. The Dead Sea trip. And we put my daughter pretty much in remission. Ever since our first trip there, hers was never spread. It's never gone away completely, but it's never spread. And mine, I've never been able to get it to stop spreading. I consider it a form of art. It's movement.

But I would like to bring up to this discussion is here in the US, I've felt a big resistance with the dermatologists against wanting to treat. I've had a few tell me they don't want to do it. They don't want to treat because the people get frustrated because there's no cure and they spend money. And then all the sudden, it spreads again, and they just rather not deal with it. So I know from many support groups I belong to that people set an appointment and come back extremely disappointed because the dermatologists don’t understand that I'd rather have less vitiligo than more vitiligo. And I want to keep treating.

And the access to the narrowband UVB, which in my personal opinion is one of the best treatments out there, needs to be affordable. In Europe, there's no big restriction on it. You can order one, and the simple handheld unit is $150. Here in the US, you have to battle the company. You have to have prescription from a doctor. You have to pay at least $350 or more because they keep getting a little bit more modern, and every year the price goes up. So I think these are real concerns. You know? The UVB works very well.

The other good about the UVB that I've noticed is if you do 15 seconds each side of your vitiligo spots every day, you can go out in the sun and not be so terribly sunburned. Like if I'm not doing the UVB treatments and I start going out in the sun, I immediately get sunburned. But if I take every morning and just do a minute in front of it, I do like

15 seconds each side, and I do it every day, I can go outside. I don't need to be plastering myself five times a day in sun lotion. I just put it on if I'm going to be on an extended stay out there. So I think things need to be expressed.

MS. BENT: Yes. No. Thank you very much. Really appreciate your thoughts on that. Let me turn to Joe on, I believe, Line 5.

CALLER JOE: Hello?

MS. BENT: Hi. Hi, Joe. Thank you for calling. I wonder if you would share with us kind of some of the thoughts you have about treatments and maybe what an effective treatment would look like for you?

CALLER JOE: I just want to say thanks for everybody taking the time and looking into this. I've had vitiligo since I've been a baby, and I'm 55 now. My mother, when I was a teen, found treatment as in just a vitamin treatment. And was taking a vitamin regimen. First, starting with liquid and then going to just the pill form. I've gotten rid of probably over 65, 70 percent of my vitiligo.

And then later in life, I slowed down. Did not take the vitamins anymore, and it started to come back. And now I'm back on the vitamin regimen. And I've got some vitiligo on my face, and I see it starting to fill in on my beard as well as around my eyes and my arms as well again. So I'm back on the vitamin regimen not under any doctor treatment plan or anything like that. Just based off of what my mother has looked up. And that seemed to do wonders for me. Not knowing if anybody's looked into a vitamin treatment or doses of how much vitamin would help with treatment at all or not.

MS. BENT: Okay. Thank you. And that actually kind of leads us right into our next polling question that we're going to go to, which is a question about besides the medical products or interventions mentioned previously, what are you doing currently to manage your vitiligo.

And the options that we have, and I will read them to you because they are very small on the screen. A, temporary cosmetic procedures, such as makeup or sunscreen, et cetera; b, dietary and herbal supplements -- and you can choose all that apply -- c, diet modifications, such as limiting alcohol consumption, a keto diet, a Paleo diet, vegan diet, et cetera; d, over-the-counter products; e, complementary or alternative therapies; f, counseling or psychological treatment; g, other therapies not mentioned; and h, not doing any treatment.

Okay. And again, since it's particularly challenging, I think, to see the answers, I will read them to you once we get a few more seconds. So it looks like the blue line is temporary cosmetic procedures, such as makeup or sunscreen. The first blue. The second, the 19 percent is dietary or herbal supplements. Then we have diet modifications. The pink is over-the-counter products. The purple is complementary or alternative therapies. F is counseling. G is other therapies not mentioned. And H, the large green at the far end is I'm not taking any therapies or treatments.

So let me turn briefly now back to our panelists and see if we have anybody who's kind of using some non-drug therapies. Anyone who's using non-drug therapies, why you decided to use them, and how is your experience?

Mary, I don't know if you want to speak to this? Is that okay? Great. If you wouldn't mind speaking to that. I believe you're muted. Perfect. Now you're not.

PANELIST MARY: Hello, everybody. This is Mary. I'm in France right now. I'm originally from Turkey. My vitiligo appeared with a tiny dot on my finger when I was 21 years old. Now I'm 39, and almost half of my skin area is now depigmented.

At the beginning, I tried a topical cortisone without much success. Three years later, I tried an unconventional therapy from a pharmacist that had trained himself with different non-conventional approaches. So he proposed a therapy combining some steam bathing with a lot of creams that we had to apply before going out into the sun or under the steamer as well as some herbs and spices that we had to consume orally. And it had really great results. I could repigment all of my face within a month's time.

It was really amazing, but the protocol was so much time consuming that it wasn't compatible with any other occupation during the day. I mean, you had to leave anything else aside and just focus on the treatment. So I just felt that the vitiligo could relapse at any time, and I thought I couldn't spend all of my life treating myself and not doing anything else. I gave up. I gave up after two months of therapy. And I decided to stop treating myself, but it was more easily said than done.

Two years ago, so rather recently, I decided to change my diet mainly. I removed all cereals and dairy products from my diet. And combined with exposure to sun, my vitiligo started to repigment very quickly. But it's impossible to maintain regular exposure to sun given the winter, the kids, the professional life, and so on. So I still continue to diet. And I see repigmentation at times when I can expose myself to sun for a few days in a row, but I'm not any more deliberately looking for the opportunity.

And what I could say for an ideal therapy for me, I mean, most of the other proposals for therapy, I filtered them -- I could say. Depending on my mood at that time, how I saw my vitiligo, if I convinced that it could actually be treated or not, and now I'm convinced that treatment for vitiligo cannot be convincing if it's simply targeting the skin unless the manifestation of vitiligo itself is very localized and specific. For my case or for cases of expanded vitiligo like mine, it's clear to me that vitiligo is only the symptom of other deregulations, either physiological or psychological if not both.

So in an ideal treatment, I would certainly look for a comprehensive approach looking for the root causes and addressing them and combining multiple strategies that do not necessarily fit within one drug if needed. Treatment proposals from the

Eastern medicines, from radical or traditional Chinese medicine are, for instance, very interesting. They do not propose one single drug. But I do not the expertise myself to judge on their merits as such.

MS. BENT: Thank you.

PANELIST MARY: If I could?

MS. BENT: Yes, please.

PANELIST MARY: And other than any treatment approach to vitiligo itself, it's very important to systematic proposals to psychological health because, I mean, everybody talked about it. This could be one of the reasons of the onset of the vitiligo, but even if it's not the reason, it has certainly effects on our psychology. So in any case, I think psychological help is essential for patients suffering from vitiligo. Thank you.

MS. BENT: Thank you. Beverly, did you want to add something briefly before we go to somebody on the phone?

MS. SMITH: Were you speaking to me?

MS. BENT: Yeah. Sorry. I thought you

had your camera on. So I wondered if you wanted to add something briefly?

MS. SMITH: No. No. Okay.

MS. BENT: Okay. Great. All right. Thank you. So let me then turn to Savannah on Line 6?

CALLER SAVANNAH: Hello.

MS. BENT: Hi, Savannah.

CALLER SAVANNAH: Hi. Hi, everyone. My name is Savannah, and I want to start by thanking you all for sharing your experiences and to the FDA for hosting this meeting.

I was diagnosed with segmental vitiligo when I was around 16, following the appearance of a halo nevus on my back. I'm now 22, and no one else in my family has or had vitiligo. It was very stagnant for a while, only spreading on the right side of my back and chest. But it's changed a lot over time. And one of the biggest things I've noticed is the correlation between stress in my life and the spread of vitiligo.

But in terms of treatments, I've tried

topical treatments, such as Protopic, Elidel, and others, which are -- for quite a while. But a lot of these creams stain absolutely everything, which makes it challenging to keep up the treatment: sheets, pillows, clothes, towels, et cetera. And I know many people cannot afford to constantly replace these items. So it's either treatment or stained belongings. So my hope is that drug developers will keep this in mind.

And in terms of accessibility, most topical treatments that I've tried are not covered by medical insurance for the purpose of treating vitiligo. So hopefully conversations such as these will allow us to make progress on this, so that vitiligans of all socioeconomic statuses can obtain treatment.

I believe it's very important to have these conversations. So awareness can be brought to vitiligo as something that is more than an aesthetic inconvenience, but rather a condition that truly does affect people's every day lives all over the world like we've heard today whether that manifests itself physically, psychologically, socially, and more. So I really appreciate all of you for hosting this meeting today. Thank you so much.

MS. BENT: Great. Thank you so much for your thoughts on that.

Let us move now to one more polling question, which is about the medical products or interventions. What are the most burdensome impacts of the treatment? And so the question is, for the medical products or interventions you use, what do you consider to be the most burdensome impacts. And you can choose up to three answers. The first one is how the medication is administered, such as topical cream or an injection; change in the pigmentation of the skin, such as color or pattern; the treatment only provides minimal benefit; the treatment is effective only for a short-term; bothersome side effects of the treatment; concerns about serious risks of the treatment; uncertainty about the long-term effects of the treatment; difficulty in accessing treatment, such as insurance or physician referral; and other negative impacts not mentioned.

And I think that we've kind of already touched on this quite a bit with our panelists and the people on the phones. But I think it's helpful just to kind of continue the discussion to really understand the impacts that a broader portion of people participating in the meeting are experiencing. So it looks like pretty much all of these impacts are burdensome and impactful to people. So I think that this really speaks to what we've heard already.

So thank you for that. I think as the polling results are coming in, I would like to really kind of ask you a little bit more about efficacy and safety. So efficacy and safety are important for any treatment. So when you think about a treatment for vitiligo, does it matter to you whether the product might improve your most bothersome symptom or whether it would have some bothersome side effects? I guess, what we're kind of asking is, would you consider improvement in -- sorry. I kind of lost my train my thought midway through there. But as far as when you're considering the benefits of a treatment and the risks of a treatment, how do you make a decision about what you would consider accepting as far as risks when you're thinking about a treatment?

I realize some of the people that we have on the line may have called in for different purposes. But for those of you waiting on the line, I'm going to turn to you in a moment to see if you have any thoughts on that.

Jay, it seems like maybe you might have a thought on that if you wouldn't mind kind of sharing that thought with us?

MR. HAMPTON: Yeah. Sure. It's just mainly just with how resourceful the treatment is and how often, where you can purchase it at, and also costs with it as well. I was very fortunate that a lot of my treatments were given to me for research purposes. Of course, that was way back in the early 2000s. I know everybody's not as fortunate to have received that right now. So that's the main thing.

And also just with a lot of the side effects with it can be very burdensome. And just having a voice with talking to your dermatologist that's an advocate for you. Provide an advocacy for these types of treatments for vitiligo. Just to keep somebody who's trying or starting new treatment to sustain it -- you know? -- so to speak and have support with it. That's all.

MS. BENT: Thanks, Jay. Stephen, did you want to say something?

MR. TAYLOR: Yes -- -- virtual connectivity interruption -- it's a major factor --

MS. BENT: Stephen, I'm having a little trouble with your audio. I don't know if others are as well. Okay.

MR. TAYLOR: Can you hear me now?

MS. BENT: Yes.

MR. TAYLOR: Okay. I was just thinking about something. Stress is a key factor for vitiligo and its spread. When I was taking treatment, the stress of taking the treatment: the drive, the waiting in line, and coming back, the three days a week, the six months of treatment, and then any future treatments from other light treatments. I think that caused my vitiligo to regress even though I was making progress because I was stressing during the treatment process.

MS. BENT: That is an interesting thought. I think Mary touched on that kind of earlier as well. So no. Thank you.

So now let me turn to Netta [ph] on Line 8 to hear from some of our phone line callers. Netta?

CALLER NETTA: Netta. Hi.

MS. BENT: Netta. Sorry.

CALLER NETTA: No, it's totally fine. So I'm 29, about to be 30. And so in two months, I would have had vitiligo for 20 years, which is a scary number. My God. But I got it when I was 10. It was like a little spot on my chin. And the thing is we went to my primary care doctor, which was the worst idea because then it spread to my chin and then my neck. And that's all where I have it.

And I started with UVB light. And like everybody was sharing, which I really appreciate, I would go three times a week after school, and my childhood was very intense because I would go after school. And I'd come back to school or go to theater. So it was very, very time consuming. And then I switched to UVA. And we thought we could snap it with UVB first because it was narrowband, more precise. And then UVA, we knew the risks. Did it anyway.

And then after a while, then we did excimer. So then I would go to Stanford three times a week. And then when I went to college, that's where it stopped because I went to Orange County. And UC Irvine had it, but then when I called the medical board, I remember whoever was on the line said, "Oh, it's a cosmetic thing." And that really pissed me off because then I said, "Okay. Whoever's on that line doesn't know. Isn't educated about it." And I thought to myself, "I couldn't get anywhere." So then I haven't had treatment.

But then my dad, he bought me that portable kit from Daavlin, and I feel so bad because I haven't used it as well. And I feel like it was a waste of money because I still have it with me. But the way it's designed, I can't cover with a sheet. And even with the light treatment, I would do the goggles, the cream on the face, the towels, everything going in. And so I still have that, and I'm curious if anyone else had Daavlin or know how to use it.

But then right now, I do Protopic, and I also bought this vegetarian tablet called Recouleur. So it's supports reappearance of color in gray hair and depigmented skin. So I thought it can't hurt. Gave that to my holistic nutritionist that tested on me. A little Eastern medicine thing. And he said it was fine.

And what's curious is I went to my dermatologist last year. A new one. I live in LA now. And what was interesting was that I think I want to tell everyone that whoever's your dermatologist, make sure they're empathetic and compassionate and care about vitiligo because the way she spoke to me was like she didn't care. You know? We all talked about the psychological, the emotional, all of that. I mean, to have your doctor not really care. I always ask this, "Are there any updates?" And she said, "Well, you've had it for almost 20 years. So I guess it's pretty old now." And hearing everybody say how long they've had it, I'm like, "That can't be an answer." Like I still feel like the body can do something. Heal itself. That was very disheartening to hear, and I'm not going to her again.

And I'm also an actor and a singer. And I go on set. And this is for the cosmetic portion, that I feel like there should be a makeup line for makeup artists who work in TV and films -- if this could be a conversation down the road one day -- where there's a makeup line that the ingredients are specifically for entertainment people with vitiligo because we've worked hard to maintain our vitiligo health. And so I don't want to Dr. Big use makeup products that I don't know what the ingredients are made of.

MS. BENT: Great. Thank you so much, Netta. We really appreciate your thoughts. Unfortunately, we're going to need to move on now to Kelly on Line 7. Kelly? Kelly?

CALLER KELLY: Hello.

MS. BENT: Hi.

CALLER KELLY: Hi. Sorry for the jump. Hi. Yes. I am so sorry. I was listening. What was the question I'm being asked to respond to?

MS. BENT: So I think that it would be really helpful for us to understand kind of from a benefit risk standpoint what would an effective treatment look like to you and what kind of side effects would you be willing to tolerate for an effective treatment.

CALLER KELLY: Okay. Okay. I can help you with that.

MS. BENT: If you have something else that you'd like to speak to, please feel free just in kind of a minute or two.

CALLER KELLY: Okay. No. I can address what you asked, and I think put my two cents in at the same time. I've had vitiligo for 23 years since I was 12. I'm currently 34. I'm an African American woman with vitiligo. And so my experience with it has been prepubescent all the way until womanhood.

And I feel that the treatment that is most needed right now is more research into the use of the cream benoquin, the treatment of monobenzone, for people of color earlier intersections of having vitiligo. What I find is that most dermatologists do not want to give people of color benoquin before they're 50 percent covered with vitiligo. But what happens in order for us to get to that point, because it's an autoimmune condition, everyone depigments at their own rate, and they're not taking into consideration the sociopsychological effects of walking around with two pigments.

And as a person of color that has this for over 20 years now, I've had the hardest time maintaining work because of my social experiences in the workplace. And it's been emotionally debilitating because I just want to take care of myself. But because of the way that current treatments are with vitiligo, they're focusing more on trying to help people repigment successfully instead of depigment successfully. And I think we need to rework that idea because we know that monobenzone works.

And I feel like helping people adjust to the changes in their appearance is going to happen either way. When Michael Jackson died, he still had benoquin on his bedside. So there's certain emotional understandings that I feel we can help the vitiligo people reach through psychotherapy and through training psychotherapists to deal with vitiligo patients and other patients with autoimmune conditions for that matter. Where I'm at personally is I finally have monobenzone, but I'm 34. And I'm underemployed because of everything that I've been through with vitiligo. And if they would have just given me the cream when I asked for it when I was 21 and in undergrad and seeing dermatologists at Howard University who specialized in vitiligo, but no they wanted to do all these treatments on me to try to help me repigment. And that wasn't what I was interested in as a patient.

So I want more research done for people of color for monobenzone treatment and for psychological therapy. I'm understand that vitiligo affects everyone that has it, and I'm not putting down any other racial ethnicity -- vitiligo. But what I'm expressing is that because it's harder to cover in darker pigmented people, it just becomes an issue of marginalization and social stratification. Therefore, you're going to have more psychological problems, and monobenzone works. It takes away the color. It's a painful process to lose your color with vitiligo anyway.

I've had a dermatologist tell me he didn't want to give me monobenzone because he wasn't sure if I could handle being white. And so there's a huge problem in the medical community with racial biases and treatment of vitiligo patients. And that was my two cents.

But research on monobenzone, how it affects the immune system but also the autonomic nervous system would be great. Because the truth is we can manage wearing sunblock for the rest of our lives, but going through multi-pigmented in the all different areas of your live, it's just emotionally exhausting. And I know that's across the board with all patients that suffer with vitiligo understand that. And the subconsciousness, you think someone can see a spot that they can't even see. Like, it's just you know? So more research --

MS. BENT: Right. Thank you. And I think that is an important point. And I think we have heard a number of times today that there is identity kind of tied to the pigmentation and the depigmentation. And it is very impactful to people. So I think you've raised some very good points. Thank you for that.

Let me turn now to our FDA panelists,

particularly, Dr. Marcus to see if you had any questions or clarifying questions that you had for our panelists or our callers please.

DR. MARCUS: Sure. Thank you, Robyn. And I just want to say that I completely respect the caller's perspective that depigmentation is sometimes the preferred goal for patients. But focusing on repigmentation, I'd like to ask people today, in the context of how well a product works, do you all have ideas about what a clinically -- in FDA speak we like to talk about clinically meaningful improvements.

And in terms of addressing diseases and providing effective treatments, progress is often made in small stepwise fashion, where initially products provide modest efficacy. Scientists and drug companies build on what has been learned from the first products that are developed, and subsequently, oftentimes, although not always, new products will have more efficacy.

In that context in this area where there is still a significant unmet medical need, if as a patient you were going to take a treatment, is there some minimal level of improvement or repigmentation that would be meaningful to you? So would any level of repigmentation for those who have lost the majority of their pigment, would that be meaningful to you? Would it be meaningful if you regained half of your pigment? If that’s the best that you could do, would you be satisfied with that as being better than no treatment? I'd just like to hear about that level of improvement that patients would accept from any treatment. Thank you.

MS. BENT: Okay. Let me start by turning to Beverly, and then we'll go to Mary.

MS. SMITH: Yes. To answer that question, I think both Lee and Stephen spoke to the area if we had choose an area, and that would be our face. I know when I was diagnosed, I said, "Well, just please don't let it come to my face." And it took it about two and a half years before it got to my face. So if there were some treatment that could bring the pigment back in our face areas, would be very helpful because that's where people see you. And they can hear you, what you're saying, if they can see a normal face when you're trying to advocate or talk about something important. Educate people on vitiligo. That's we do now. We're all advocates. So that would be an area that I think that we would all be happy if we can get the pigmentation back into our faces.

MS. BENT: Thanks, Beverly. And let me just ask a quick follow-up question. So when Dr. Marcus was talking about maybe like 50 percent pigmentation back or when you think about getting the pigmentation back, can you speak about what would be a success? Would it be kind of like half the pigmentation back, or are you thinking kind of complete? I mean, obviously, complete would be wonderful. But would 50 percent be something?

MS. SMITH: To me or someone else?

MS. BENT: You. Just really quick at the end of your comments.

MS. SMITH: I think 50 percent would

not -- for the facial area, if we can get more than the 50 percent, you can do other with makeup. But I decided not to wear makeup at all period. But in the facial area, it can be wearing makeup can do the other part of it, and it wouldn't look so much like you wearing makeup, which many people do. I don't anymore at all period. But I think more than 50 percent area in the face would be helpful.

MS. BENT: Great. Thank you. Now let me turn to Mary and then Stephen and then Vimla and Priyanka. And then we'll go back to the phones.

PANELIST MARY: Yes. To me, also the face is very important. I think we will all agree about this. And also, I mean, face and the continuity, somewhat the neck and the neckline, because, I mean, where we end the makeup somewhere, there's a greater gap of color between the makeup and not makeup part.

But I think in efficacy of the treatment is not only about how much recovery of pigment it allows, but it's also about how long this recovery will last. Because most of the treatments do bring improvement, I mean, not every treatment can work with everybody. But there are some treatments that will work with some people. But even in these cases, when we stop the treatment, it will all come back somehow slower or quicker. So it's also very important. I mean, the efficacy question for me is also the lasting effect of the treatment if possible.

MS. BENT: That's helpful too. Thank you. Stephen?

MR. TAYLOR: I'm going to underscore what she said at the end. I was thinking the same thing too. I want a qualifier in there. Because every time I had improvements and stopped taking treatments, I have lost what I'd gained. I don't need to go through an emotional rollercoaster ride. So I want a hundred percent guarantee. Okay? I know that's asking for a lot. From my experience, I just don’t want to lose what I have gained because I've gone through this process so many times.

And so I've got to rephrase the

question as a qualifier. If we can guarantee a high percentage of efficacy and it is going to stay that way, then we'll have that conversation.

MS. BENT: Very good. Thank you. And now let me turn to Vimla and Priyanka.

PANELIST VIMLA: Thank you for that question. I just wanted emphasize that we definitely want a high percentage. So typically, in the 80 to 100 percent, mainly because there's also a pattern of progression of the vitiligo. So your baseline assessment is constantly changing, which is why you want a very high degree of repigmentation and permanent repigmentation at very high numbers far greater than 50 percent just because the spread and the rate of spread is much higher than the rate of repigmentation. So that is why you want to hit it even before it spreads. So I would say a pretty high number. Like 80 to 100 percent.

Priyanka, do you want to add anything?

PANELIST PRIYANKA: In addition to what some other panelists mentioned earlier, I think location is really important. So I would much rather prefer that results rise on my face as opposed to other parts of my body just because those are the most visual areas and those are the areas that people tend to judge. That's all.

MS. BENT: Great. Thank you very much. Now let me turn to Betty on Line 8.

CALLER BETTY: Good afternoon. I just kind of wanted to answer the question the doctor was proposing as far as what would you consider success. I have had vitiligo for 45 years, and I have it like over 75 percent of my body, mostly my face is impacted. I would say in order to gauge that, you would probably do a demographic and ask people of different groups how much do they have over their entire body. And then kind of give them a timeline as to the treatment. You know? In six months, if you could get 25 percent back, would that be successful to you? You know? In 12 months, if you could get 50 percent back, would that be something you would interested in doing? Not everyone is interested in getting the repigmentation treatment. So that will be something that will be helpful to people with vitiligo. So I would say to do something in that regard to kind of assess what the needs are.

MS. BENT: Great. Thank you, Betty. Really appreciate that. Let me turn now briefly to Shannon to see if we have any comments from people online regarding this question.

MS. COLE: Thanks, Robyn. We've received several comments online about clinically meaningful treatment benefits. And they're all kind of differing based on the individual's experience.

But one individual said that they would love to regain even half of their pigment as long as the effects and the process were not too arduous. And on the other hand, some had expressed that they are looking for all or nothing in a treatment and that consistency is very important in terms of that unknown factor of possibly losing pigmentation in the future.

Another commenter stated that they're now 43 years into their journey with vitiligo, and they are not interested in small improvement treatment. But 50 percent or higher would be very beneficial, especially if the treatment was easy. If it was a cream that they have to use twenty hours a day, seven days a week, then the 50 percent would not be worth it to them.

Another individual expressed that they have universal vitiligo and a hundred percent natural skin depigmentation. So they would only consider a treatment that repigments, at least, 80 percent of their skin. And they would also consider a higher risk treatment if it was effective at putting their vitiligo into remission for a longer period of time. They would also love to see a treatment for the repigmentation of their hair.

And a few other commenters also mentioned that their face is probably their first priority in terms of treatment and seeking that repigmentation.

MS. BENT: Okay. Thanks, Shannon. Let's move on now. Actually, we have a hypothetical scenario that kind of touches on this, and we'll kind of give us a good idea of what people throughout our webcast are thinking about this.

So if we can move on to Hypothetical 1, which is a new skin cream. Okay. So I am going to read the hypothetical scenario to you. So imagine that a new topical cream, not a steroid, indicated to treat vitiligo has recently been approved by the FDA. Your doctor believes that you or your loved one may be a good candidate for this medication. The topical cream needs to be applied once a day. Research in animals and people show that this treatment may improve pigmentation by up to 50 percent. Some common side effects for this therapy may include redness and irritation at the application site, mild acne, and burning. Rarer but more serious side effects may include fever, pain during swallowing, insomnia, nausea, and increased heart rate. What first thoughts come to your mind as you hear this scenario? What questions would you ask your doctor about this treatment?

And so our question to you first is given the risks and benefits, would you be interested in taking this medication? And the options are yes, no, or maybe. Okay. And it looks like we’re pretty split about that with 43 percent of people saying yes, about 25 to 30 percent saying no, and 30 saying maybe. So this is helpful for us to hear. It would also be helpful for us to know kind of what degree of risks are you willing to accept for an effective treatment: risks such as immunosuppression or potential other challenges as we look at that.

So while we're waiting for the results to kind of stabilize, let me turn to just a few more people that we have on the phone. And let me see. I'm sorry. I've lost my list of people on the phone. Do we still have Masooma on Line 10?

CALLER MASOOMA: Yes. I am still on the line. Can you hear me?

MS. BENT: Great. Thank you so much for your patience and for holding. So I wonder if you would be willing to speak a little bit to the thoughts about treatment and effective treatments and what would that look like and side effects you'd be willing to kind of deal with. But if you had something else you'd like to speak to, we'd be happy to hear that in the next minute or two.

CALLER MASOOMA: Yes. Thank you so much, again, for the opportunity to voice our opinions to both the FDA and the organizers of this meeting and all of the patients with vitiligo that have already shared their stories.

I wanted to touch on a few different points. In terms of the clinical outcomes and looking at optional therapies for future, I think going back to the 50 percent option of repigmentation. Again, I think this can vary quite a bit. Again, I would agree with the rest of the speakers that who already spoken before, the face is very important. So I think 50 percent Is not acceptable to me. I really would like that area to be higher.

And of course, the other issue is that repigmentation pattern. For somebody's who has lost a lot of pigment already, regaining 50 percent might make them actually look perhaps worse in terms of their own opinion versus being more uniform in color. So I think that's a consideration.

The other thing is the duration of pigment gains and how long the effect will last as well should be consider because, again, we're kind of tethering back and forth between having repigmentation and then losing it again. And I think bringing sort of the cause of vitiligo and perhaps autoimmunity in general becomes very important in this regard because the issue is that we're always playing catchup with the condition. So I think really putting more research and understanding into the causes of the disease, I think, can help in that regard. Because we're not just repigmenting, we're also slowing the progression or perhaps even halting additional slayers.

The other thing I want to mention also is that considering some of the other options that are already in development that are being looked at vitiligo, they carry significant side effects, such as immunosuppression, that you've already mentioned. So if I have a risk of a very severe infection down the road or perhaps even cancer, that really makes me rethink, "Does my immune system need to be suppressed via an oral medication versus a topical?" So I would be more open to a topical medication if that is very effective. But again, if the oral treatment had a very favorable benefit risk profile, I would definitely consider that as well. But I think, again, some of these need to be looked at more long-term in terms of the side effects as well because we don't want to just be addressing that now and having some major other issues down the road.

One other thing I want to implore the FDA to do also is in terms of looking at this from a holistic perspective, many of us have already mentioned that vitiligo carries vast and varied negative consequences for many of us, including physical, psychological, emotional, et cetera. So I think, again, this may be the first step, but really bringing together some of the other regulatory agencies or government agencies including academicians, researchers, et cetera, and pharmaceutical companies to look at this and provide more answers in what really may be effective in stopping the progression of the disease not just looking at treatment options once it's already developed. And again, we're playing catchup. So thank you, again, for the opportunity to comment.

MS. BENT: Thank you so much. That was really very insightful comments. I appreciate those. Let me turn to Denise on Line 5.

CALLER DENISE: Hi. Can you hear me okay?

MS. BENT: Yes, ma'am.

CALLER DENISE: I'm Denise from Indianapolis, Indiana. And I'm the president of Fearfully and Wonderfully Made IDC Vitiligo Community. But I was diagnosed 16 years ago. In fact, I was 50 when I first had my first spot, went to four different doctors, and got four different skin biopsies, and finally got the right diagnosis. I was misdiagnosed first.

But I just want to say really fast that I agree with everything, especially the last lady in front of me what she just said about this. She was spot on. But I wanted to bring up a couple of things that in my group that I've had people share with me that haven't been shared yet. One, a person who had vitiligo in my group, her vitiligo and stopping her makeup was the straw that broke the camel's back. And she got a divorce. And then another person in my vitiligo group, she needs to write a book. But because of her, I now carry a doctor's statement in my car because of the political climate today with the police thing and things like that. I don’t want to be stopped, and somebody look at my license and look at my picture on my license, which does not look like my face anymore, and get arrested because they think I'm trying to be somebody that I'm not.

So those are all things that are just really so important. And why, like Perry said, we really need you guys to really pay attention. And I'm so thankful for this avenue and the fact that you're doing this right now. So thank you so much for letting me get on and letting me share this. Okay? And I'm going to still be boots on the ground in Indiana spreading awareness about vitiligo.

MS. BENT: Great. Thanks so much, Denise. Really appreciate your call.

So it looks like we're coming up on the end of the meeting. Let me turn back to our panelists. I don't know if we have anybody who wants to share any final thoughts. Lee Thomas, I know you had raised your hand a bit earlier, and I hadn't been able to get to you. Did you have any final thoughts that you wanted to share with us before we kind of wrap up the meeting?

MR. THOMAS: I'm trying to unmute myself.

MS. BENT: You're unmuted. Your video is not on, which is fine. We can still hear you.

MR. THOMAS: Okay. All right. There

is it. You guys allowed me to start my video. Thank you. The only thing I want to say is I heard -- I think it was -- Vita [ph] from California or Vetta [ph] from California -- she asked about makeup. And I have to put makeup on every day. So I found a couple of products that actually work. And one of them is Cover FX. It was made for rosacea to cover rosacea, but it has the pigment in the makeup. Actually, works pretty good.

The last thing I'll say is I just really appreciate this. I really do. I've traveled around, and this is the first time I'm sitting on a panel with people from the FDA or I'm part of a panel with people from the FDA. So I'm very encouraged by this day. And it's been emotional, and it's been insightful. And I just want to say thank you, Robyn, and thank you to the people from the FDA for letting me be a part of it. And I'm anxious to see what happens next.

MS. BENT: Thanks so much. Let me go to Mary and then Jay for final comments before we turn it over to Dr. Marcus for closing remarks. Mary?

PANELIST MARY: You can hear me better now. Thank you for this meeting. It was very enlightening to hear the other vitiligo patients' experiences. I really would like to underline the importance for me, at least, to work on the root causes of vitiligo because now we are all focusing on symptomatic treatments because that's what we are interested in. I mean, we try to look better. We try to feel self-confident about the way we look. Of course, this is understandable. But I think we do have to look at the root causes and try to find the treatments that are going to heal the root causes because the skin is just manifesting something that's probably going wrong somewhere else. So I really would like to see more research on the root causes of vitiligo. Thank you.

MS. BENT: Thank you. And Jay?

MR. HAMPTON: Yes. Lastly, just to put on there, I know some of that wasn't discussed and I know that worked for me is the last-ditch type of treatment, all of us that's watching this, is acceptance. You know? Once we accept who we are and love who we are, that gives us a driving force to keep going on. And the support that we have with this type of FDA panel and all this through Facebook that wasn't around when I first came on eons ago has helped me a whole lot. So whether we get a treatment or a cure or not, just knowing I'm not in this battle by myself -- to at least be grateful I'm waking up and keep going on. I can share experiences in strength and hope and my depression and all that stuff with people, my support group, and know that I'm not talking by myself. So I thank you all again. Much love.

MS. BENT: Thanks, Jay. I can't think of a better way to kind of end the panel session. So thank you all for an amazing meeting. Your sharing today has really provided us with valuable insights. And again, if we weren't able to get to your comments today, that doesn't mean they're not valuable. We do really want to hear them. So please consider sharing them to the federal register, and we will also include them in the Voice of the Patient report.

In addition, as a reminder, we will be launching the crowdsourcing website later on this week hopefully. And so we'll share that information when that is launched with you, so that you can continue to share your experiences with us. And those who are not watching this in real time but who are watching this as a recording, hopefully, you'll be watching it within the next week or so and will also be able to participate in the crowdsourcing.

With that, I'd like to turn the mic over to Dr. Marcus, again, from the Center for Drug Evaluation and Research here who will provide us with closing remarks. Dr. Marcus?

DR. MARCUS: Thank you. Thank you, everybody, for participating in this meeting today and for sharing your stories, experiences, and perspectives. Usually, I like to provide a broad overview of what I've heard, and we've heard so much today that's it's challenging for me to put it all together.

I think that anybody listening today would understand the tremendous impact that vitiligo has on people's lives. I don't think that there's any denying that it can result in the loss of even one's identity, what you see when you look in the mirror. It impacts the way that others interact with you. And we heard in some cases that people were unable to get employment, that they are avoided, that they're bullied.

And what's particularly difficult to hear about that is that at the same time for some of you, you have difficulty having your disease taken seriously by physicians who view it largely as a cosmetic condition and are reluctant to treat because they believe that your expectations will not be met and that it will be an exercise in frustration. I'm really sorry to hear that for all the people who have experienced that.

We've also heard from you about treatments and the impacts that some of the treatments can have on your lives. Making it impossible to do other activities, such as work or care for yourself in other ways. That's certainly not the kind of treatment burden that anybody wants to have. We also heard about the wish to have cures as well as prevention of progression of disease. I want to make sure that you all understand that you were heard today. And that you understand that this kind of dialogue is important, not just for us, but also for the drug companies, the researchers, and other medical product developers who are also here today.

So again, I just want to let you know we're all listening to what you have to say. And I hope that the information you provided to us today helps to advance the science and development of new treatments for those who would like to have them. Thank you very much.

MS. BENT: Thank you, Dr. Marcus. Thank you, everybody. Have a wonderful day. Goodbye.

(Whereupon, the meeting concluded at 2:26 p.m.)

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